

EXHIBIT M

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1 UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
2 CAMDEN VICINAGE
3 IN RE: VALSARTAN, LOSARTAN)
AND IRBESARTAN PRODUCTS)
4 LIABILITY LITIGATION) MDL NO. 2875
_____))
5) HON. ROBERT B.
THIS DOCUMENT RELATES TO:) KUGLER
6)
ALL ACTIONS)
7 _____
8
9
10

Monday, October 4, 2021

11
12 CONFIDENTIAL INFORMATION
13 SUBJECT TO PROTECTIVE ORDER

14
15

16 Remote Video-Recorded Oral
Deposition of GEORGE JOHNSON, Ph.D. held at
17 the location of the witness commencing at
9:07 a.m. BST on the above date, before
18 Michael E. Miller, Fellow of the Academy of
Professional Reporters, Certified Court
19 Reporter, Registered Diplomate Reporter,
Certified Realtime Reporter, and New Jersey
20 Certified Court Reporter No. 30XI00242200.
21
22

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<p style="text-align: right;">Page 10</p> <p>1 -----</p> <p>2 PROCEEDINGS</p> <p>3 October 4, 2021, 9:07 a.m. BST</p> <p>4 -----</p> <p>5 THE VIDEOGRAPHER: We're now on</p> <p>6 the record. My name is Joseph Viner.</p> <p>7 I'm a videographer from Golkow</p> <p>8 Litigation Services.</p> <p>9 Today's date is October 4th,</p> <p>10 2021, and the time is 9:07 a.m.</p> <p>11 This video deposition is being</p> <p>12 held in London, U.K., in the matter of</p> <p>13 Valsartan, Losartan and Irbesartan</p> <p>14 Products Liability Litigation</p> <p>15 in the United States District Court of</p> <p>16 New Jersey.</p> <p>17 The deponent is Dr. George</p> <p>18 Johnson.</p> <p>19 The court reporter today is</p> <p>20 Mike Miller, and will now swear in the</p> <p>21 witness.</p> <p>22 ///</p> <p>23 ///</p> <p>24 ///</p>	<p style="text-align: right;">Page 12</p> <p>1 to answer. That way the record can be clear.</p> <p>2 We can't speak at the same time, okay?</p> <p>3 A. That's okay. Thank you for the</p> <p>4 advice, okay.</p> <p>5 Q. And doing this by Zoom,</p> <p>6 sometimes there's a little delay with the</p> <p>7 connection, so to speak, so we have to be</p> <p>8 really cognizant of that. I think we'll</p> <p>9 notice if there is a delay as we go on this</p> <p>10 morning, and then we'll have to obviously</p> <p>11 accommodate it if there is.</p> <p>12 If you don't understand a</p> <p>13 question that I ask, please let me know so I</p> <p>14 have the opportunity to rephrase it for you.</p> <p>15 A. Understood.</p> <p>16 Q. If you answer a question, I'm</p> <p>17 going to assume you understood it, so if you</p> <p>18 don't understand what I'm asking, please let</p> <p>19 me know that, okay?</p> <p>20 A. Okay.</p> <p>21 Q. Now, did you meet with the</p> <p>22 attorneys for the defendants prior to today?</p> <p>23 A. Yes, I did.</p> <p>24 Q. When did you meet with them?</p>
<p style="text-align: right;">Page 11</p> <p>1 -----</p> <p>2 GEORGE JOHNSON, Ph.D.,</p> <p>3 having been duly sworn,</p> <p>4 testified as follows:</p> <p>5 -----</p> <p>6 EXAMINATION</p> <p>7 -----</p> <p>8 BY MS. BOGDAN:</p> <p>9 Q. Good morning, Dr. Johnson. My</p> <p>10 name is Rosemarie Bogdan, and I'm going to be</p> <p>11 asking you some questions today. I represent</p> <p>12 the plaintiffs in the action that has been</p> <p>13 commenced.</p> <p>14 Have you had your deposition</p> <p>15 taken before?</p> <p>16 A. I have not.</p> <p>17 Q. Okay. In any capacity, in any</p> <p>18 litigation, this is the first time?</p> <p>19 A. This is the first time.</p> <p>20 Q. Okay. So since it is your</p> <p>21 first time giving a deposition, one thing</p> <p>22 that I would ask, and I'm sure the court</p> <p>23 reporter would ask, is that you wait until</p> <p>24 I'm done asking my question before you begin</p>	<p style="text-align: right;">Page 13</p> <p>1 MS. LOCKARD: Did you say when</p> <p>2 or where?</p> <p>3 MS. BOGDAN: When.</p> <p>4 MS. LOCKARD: Sorry, I couldn't</p> <p>5 hear.</p> <p>6 A. When? We met -- I'll have to</p> <p>7 look at that. We had an official meeting</p> <p>8 yesterday and the day before, and we arrived</p> <p>9 day before that. Is that correct?</p> <p>10 BY MS. BOGDAN:</p> <p>11 Q. Okay. And how many hours did</p> <p>12 you spend with the defense counsel?</p> <p>13 A. During this current trip?</p> <p>14 Q. Yes.</p> <p>15 A. During this current trip, I</p> <p>16 would say over the four days, including</p> <p>17 today, it would be about 40 hours. We've</p> <p>18 been spending a lot of time. That's</p> <p>19 including my time as well.</p> <p>20 Q. And when you say 40 -- you said</p> <p>21 four-zero, 40 hours?</p> <p>22 A. That's including my work on</p> <p>23 this -- on this project as well as our</p> <p>24 meetings together.</p>

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1 Q. And so what were the hours of
2 your meetings together in the last few days?
3 A. In the last few days, we
4 spent -- we met yesterday at their office in
5 Greenberg Traurig from 10:30 until 4:00, and
6 the previous day was 11:00 until 5:00.
7 Q. Now, did you spend time on your
8 own preparing for the deposition?
9 A. Yes, I did.
10 Q. And how many hours did you
11 spend preparing for the deposition on your
12 own?
13 A. On my own? During this trip or
14 altogether?
15 Q. During this trip.
16 A. During this trip. On top of
17 that, I spent an additional maybe 4 hours
18 both of those days, and the previous day, I
19 would say 10 hours preparing, reading
20 everything. I like to prepare for things, so
21 lots of reading.
22 Q. And what materials or documents
23 did you review to prepare for the deposition?
24 A. The recent documents that I've

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1 been looking at are the depositions from the
2 other expert witnesses. I've spent a lot of
3 time on those. I've refreshed my memory of
4 my own publication, of my own report. So
5 those have been the big ones.
6 And then critiquing some of the
7 key publications which support or which I
8 critique in my report as well, so mainly
9 those ones.
10 Q. Did you keep note of the key
11 publications that you reviewed to prepare for
12 your testimony today, meaning the identity of
13 them?
14 A. They're all contained within
15 the list that you have.
16 Q. I'm asking specifically which
17 ones they are.
18 A. I did not keep a list of those.
19 Q. Do you have a list in your mind
20 of the publications or studies that you view
21 as key publications in this case?
22 A. In my mind is my 2021
23 publication around this topic. Another one
24 would be the Peto study on the cancer

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1 bioassay dose response. Another one would be
2 the OECD guideline and the cancer bioassay,
3 and then I tried to keep up to date, so the
4 most recent expert witness depositions would
5 be the key ones I've been looking at over the
6 last few days.
7 Q. Okay. I did pick up that you
8 mentioned the Peto study. I'm assuming you
9 said Peto, P-E-T-O?
10 A. Correct.
11 Q. And then there was a second one
12 that you mentioned that was -- mentioned the
13 words "guideline" and "bioassay," but I don't
14 believe I heard the author or the entity that
15 did the study.
16 A. For the videographer, if you
17 say it very slowly, OECD. They provide the
18 guidelines for all genetic toxicity assays
19 and cancer bioassays, and then they need to
20 be abided to. So I revised those.
21 Q. So you're speaking of the
22 guidelines?
23 A. Correct, the OECD guidelines.
24 Q. Now, who is in the room with

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1 you there today?
2 A. Victoria Lockard, Steve Fowler.
3 I heard the names --
4 THE WITNESS: But you're --
5 MS. GOLDENBERG: Marlene
6 Goldenberg. I'm on Rosemarie's team.
7 THE WITNESS: Marlene
8 Goldenberg. I know, but apologies.
9 A. And the videographer.
10 THE WITNESS: Apologies for not
11 remembering your name as well.
12 MS. LOCKARD: Joe.
13 A. So did you get that? So
14 there's four of us. Hopefully you've heard
15 those names, and myself.
16 BY MS. BOGDAN:
17 Q. Do you have any documents with
18 you today?
19 A. I do.
20 Q. Okay. What documents do you
21 have with you today?
22 MS. LOCKARD: You can say
23 what's in front of you.
24 A. What's in front of me is my

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1 report and my publication and my CV, and we
 2 have boxes of the list of other relevant
 3 details that you have -- you have the list
 4 of, I think.
 5 MS. LOCKARD: Those are my
 6 boxes.
 7 THE WITNESS: Those are your
 8 boxes.
 9 MS. LOCKARD: Counsel's boxes.
 10 THE WITNESS: We have counsel's
 11 boxes too.
 12 BY MS. BOGDAN:
 13 Q. And the counsel boxes, they
 14 were not yours, right? That's not your
 15 records that you brought in as part of your
 16 file.
 17 A. Correct.
 18 Q. And then I'm assuming you just
 19 have the -- you have the videographer there
 20 and you have the Zoom open on a computer? I
 21 can't quite see the setup.
 22 A. This might take a bit longer to
 23 explain. So we have the computer in front of
 24 me that I'm speaking to you on via Zoom. We

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1 have the videographer at the end of the room
 2 with the camera to record everything. And
 3 that's why I keep looking, to ensure that
 4 during the video -- yeah. Is that enough
 5 detail?
 6 Q. Yep, that's good.
 7 Do you have any type of a cell
 8 phone there with you that you're interacting
 9 with?
 10 A. I do not.
 11 Q. Okay. And you're not
 12 interacting with the computer, correct?
 13 A. Correct.
 14 MS. BOGDAN: If we could pull
 15 up and mark as Exhibit 1 the notice to
 16 take the videotaped deposition of
 17 Dr. Johnson.
 18 (Whereupon, Deposition Exhibit
 19 Johnson-1, Notice To Take Videotaped
 20 Oral Deposition, was marked for
 21 identification.)
 22 MS. GOLDENBERG: Can you turn
 23 your camera on? It will be easier to
 24 see if you have any objections, but

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1 the depo protocol does require that
 2 cameras be turned on for anybody else
 3 in the room.
 4 MS. LOCKARD: Not if there's
 5 counsel in the room. That's for
 6 remote.
 7 MS. GOLDENBERG: Rosemarie is
 8 remote.
 9 MS. LOCKARD: I'll turn it on,
 10 but I don't agree that that's
 11 required.
 12 I just put in front of
 13 Dr. Johnson a hard copy of his notice
 14 of video deposition, for the record.
 15 BY MS. BOGDAN:
 16 Q. Dr. Johnson, do you see that
 17 document that's been marked as Exhibit 1?
 18 A. I see the document on Zoom, and
 19 I also have a hard copy.
 20 Q. Have you seen that before?
 21 A. As far as I can recall, I have,
 22 and I've seen many documents, but yes.
 23 Q. Turning your attention to the
 24 third page of the exhibit, which is -- begins

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1 with Exhibit A.
 2 A. Okay. I can see it. Thank
 3 you.
 4 Q. That requests certain documents
 5 be produced?
 6 A. Yes, I can see this. And just
 7 to reconfirm, I definitely have seen this
 8 document.
 9 Q. All right. And did you go
 10 about collecting the things that are itemized
 11 here on Exhibit A?
 12 A. I did, and I'm confident with
 13 the list.
 14 Q. So you produced all of your
 15 invoices and billing records for this matter?
 16 A. Correct.
 17 Q. With regard to the second
 18 itemized request, did you have any notes that
 19 you produced?
 20 A. I did not.
 21 Q. And you didn't have any notes
 22 to produce?
 23 A. No. My understanding of this
 24 topic was included in the report, and there

<p style="text-align: right;">Page 22</p> <p>1 was no notes surrounding that.</p> <p>2 Q. So other than your report that</p> <p>3 you wrote, there are no other notes or</p> <p>4 summaries or any other writings that you took</p> <p>5 as part of your work in this matter?</p> <p>6 MS. LOCKARD: Objection, asked</p> <p>7 and answered.</p> <p>8 A. So my response again is:</p> <p>9 Correct, there are no additional notes.</p> <p>10 BY MS. BOGDAN:</p> <p>11 Q. And did you produce copies of</p> <p>12 all materials, documents and articles that</p> <p>13 you relied on for your opinions that you're</p> <p>14 providing in this matter?</p> <p>15 A. Yes, that is correct.</p> <p>16 Q. Are there any textbooks that</p> <p>17 you're relying on for your opinions in this</p> <p>18 matter?</p> <p>19 A. There are no textbooks that I'm</p> <p>20 relying upon for my opinion, but I do read</p> <p>21 textbooks.</p> <p>22 Q. I know you read textbooks, but</p> <p>23 I'm sorry, the connection is a little bit</p> <p>24 fuzzy. Did you say that there are no</p>	<p style="text-align: right;">Page 24</p> <p>1 further instances, will this also</p> <p>2 appear in that additional link for me</p> <p>3 to look at in an online way, or do we</p> <p>4 rely on my hard copy? Thank you.</p> <p>5 MS. LOCKARD: You need to be</p> <p>6 able to pull up the link and --</p> <p>7 THE WITNESS: Is that this?</p> <p>8 Would I just go over to -- apologies</p> <p>9 for this.</p> <p>10 TRIAL TECHNICIAN: No worries.</p> <p>11 Just remember you may need to hit F5</p> <p>12 to refresh the browser to see the</p> <p>13 document.</p> <p>14 THE WITNESS: Excellent. So</p> <p>15 it's Exhibit 2, after the refresh, I</p> <p>16 have that. Brilliant. And I have a</p> <p>17 hard copy. Thank you very much.</p> <p>18 MS. BOGDAN: Have we marked</p> <p>19 that as Exhibit 2?</p> <p>20 THE STENOGRAPHER: Yes.</p> <p>21 BY MS. BOGDAN:</p> <p>22 Q. Now, does that Exhibit 2 report</p> <p>23 contain all your opinions you intend to offer</p> <p>24 in this matter?</p>
<p style="text-align: right;">Page 23</p> <p>1 textbooks you relied on?</p> <p>2 A. There were no textbooks I'm</p> <p>3 relying on for my opinion presented in the</p> <p>4 report, but I do read textbooks.</p> <p>5 Q. Now, did you prepare a report</p> <p>6 in this case?</p> <p>7 A. I did prepare a report in this</p> <p>8 case.</p> <p>9 Q. Do you have a copy of it there</p> <p>10 in front of you?</p> <p>11 A. Yes, I do.</p> <p>12 Q. And is that what was served as</p> <p>13 an amended report on October 1st, 2021?</p> <p>14 A. As far as I'm aware, that's</p> <p>15 correct.</p> <p>16 MS. BOGDAN: Can we please pull</p> <p>17 up the doctor's amended report and</p> <p>18 mark it as Exhibit 2.</p> <p>19 (Whereupon, Deposition Exhibit</p> <p>20 Johnson-2, 10/1/21 Johnson Expert</p> <p>21 Report, was marked for</p> <p>22 identification.)</p> <p>23 THE WITNESS: Apologies.</p> <p>24 Clarification. In this instance and</p>	<p style="text-align: right;">Page 25</p> <p>1 A. Not just my opinions in the</p> <p>2 report, but I have additional knowledge that</p> <p>3 may come out during this deposition, so it</p> <p>4 may not contain those opinions. But I'm very</p> <p>5 confident of all my opinions presented in</p> <p>6 this report.</p> <p>7 Q. And when you say I may have</p> <p>8 additional knowledge that will come out</p> <p>9 during this deposition, what additional</p> <p>10 knowledge are you referring to?</p> <p>11 MS. LOCKARD: Objection, form,</p> <p>12 vague, ambiguous.</p> <p>13 A. We will see during the</p> <p>14 deposition, if there's a question that I can</p> <p>15 expound upon beyond that presented in my</p> <p>16 report, then I will do so.</p> <p>17 BY MS. BOGDAN:</p> <p>18 Q. Doctor, when you said</p> <p>19 additional knowledge, I was -- are you saying</p> <p>20 that because there's something that you know</p> <p>21 now that you have learned since authoring</p> <p>22 this report that you did not include that</p> <p>23 would further support your opinions?</p> <p>24 A. That is not correct. I</p>

<p style="text-align: right;">Page 26</p> <p>1 included all of the information within that 2 report, but during reading the depositions of 3 other expert witnesses, I've critiqued 4 further detail and realized that some of 5 those opinions can be -- can be critiqued 6 quite heavily based on my understanding, but 7 not all of that is presented in this report. 8 Q. And which depositions of expert 9 witnesses are you speaking to particularly? 10 A. I forget the name of the one 11 I've quite recently -- where there was 12 critique and a long explanation around the 13 IARC findings that are very historical. I've 14 read those and have additional information to 15 critique and reject those obsolete -- that 16 obsolete report. 17 Q. And what report are you 18 referring to being obsolete? 19 A. I forget the date. I think 20 it's in the '70s from the IARC, the 21 International Agency for the Research of 22 Cancer, I think. The IARC or a subset of the 23 WHO, on NDMA. 24 Q. Are you referring to the 1978</p>	<p style="text-align: right;">Page 28</p> <p>1 invoice on this project, including this 2 deposition preparation. So a subset of that 3 time will be on preparation of that report. 4 Q. So there's an invoice for time 5 that you have already spent that has not yet 6 been prepared and sent to the defendants? 7 A. That is correct. 8 Q. Now, the amended report dated 9 October 1st, 2021, what changes did you make 10 in the report? 11 A. I cannot be clear on those 12 changes at the current time. 13 Q. What prompted making those 14 changes or serving an amended report? 15 A. They are typographical changes 16 surrounding references where there was not 17 complete references, so it was all around 18 referencing to ensure that everyone had a 19 precise list of references. That was the -- 20 that was the changes. That was the 21 amendments, as far as I understand. And I 22 have -- I hope I've got a good memory, and 23 that's how I remember it. 24 Q. Now, in the text of the report</p>
<p style="text-align: right;">Page 27</p> <p>1 monograph regarding NDMA published by IARC? 2 A. Yes. 3 Q. Any other critiques that you're 4 aware of as you sit here today based upon 5 reading of the deposition transcripts? 6 A. Not that I'm aware of today, 7 but I've been working on this topic my whole 8 career, and I will have additional 9 information when asked. 10 Q. Now, the report that's in front 11 of you that's been marked Exhibit 2, did you 12 write that report yourself? 13 A. Yes, I did. 14 Q. Did you have the assistance of 15 a graduate student or anyone -- did anyone 16 assist you in writing it? 17 A. No, they did not. 18 Q. How much time did you spend 19 writing the report? 20 A. Within the invoices, the report 21 is discussed, so the invoices that cover 22 reports within the statement cover it. And 23 in addition to that, I've spent another 24 approximately 130 hours since that last</p>	<p style="text-align: right;">Page 29</p> <p>1 itself, you have references which are 2 primarily in the footnotes, correct? 3 A. Correct. I saw this as a good 4 way of presenting the references. 5 Q. And then there's an Exhibit A 6 to the report, which is your CV, correct? 7 A. I can see -- yeah, I can see my 8 CV. 9 Q. Okay. Is that your most recent 10 CV? 11 A. Correct. In addition to 12 updating the report, I updated my CV with 13 recent publications. I've been publishing a 14 lot recently and wanted to ensure that you 15 had seen those publications within my CV. So 16 that was another amendment, to address that 17 last question, as well. 18 Q. And then there's an Amended 19 List of Materials Considered, correct? 20 A. As far as I'm aware, that's 21 correct. 22 Q. Who prepared the Amended List 23 of Materials Considered? 24 A. I prepared much of the</p>

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1 information within that list, and the final
2 list was prepared by GT.
3 THE WITNESS: Am I allowed to
4 call them GT?
5 MS. LOCKARD: Sure.
6 THE WITNESS: Thank you.
7 BY MS. BOGDAN:
8 Q. GT, Greenberg Traurig?
9 A. Correct. Is it okay for me to
10 say GT from here onwards?
11 Q. That's fine.
12 A. Thank you.
13 Q. As long as the record reflects
14 what GT stands for, that's absolutely fine.
15 And what documents were added
16 to the Amended List of Materials Considered?
17 A. I'm unaware of the exact
18 details, and it would be the updated expert
19 depositions and things of that effect.
20 Q. Did you read all of the expert
21 deposition transcripts that are reflected?
22 A. I considered all of them and
23 read in detail at least half of them.
24 Q. Can you tell me which ones you

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1 read in detail?
2 A. The -- my critique of the ones
3 I read in detail is contained in my report,
4 and the more recent ones are the ones related
5 to my understanding of genetic toxicology,
6 risk assessment and so on.
7 Q. I was looking for, Dr. Johnson,
8 which of the deposition transcripts you read
9 in detail, and they're reflected on page 1 of
10 your Amended List of Materials Considered?
11 A. I do not have that list in
12 front of me at the current time.
13 MS. LOCKARD: He does now. I
14 just handed him the amended list.
15 A. I do now.
16 BY MS. BOGDAN:
17 Q. I believe also it's being
18 displayed on the screen for you.
19 A. Oh. Sorry, I'm still on
20 Golkow. Thank you. I've gone back to Zoom.
21 I now have the information in
22 front of me, and I will --
23 MS. LOCKARD: There's no
24 question pending.

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1 THE WITNESS: There's no
2 question pending. Apologies. I now
3 have that in front of me.
4 BY MS. BOGDAN:
5 Q. Okay. I do believe there was a
6 question. What I asked was: Which of the
7 deposition transcripts did you review in
8 detail?
9 A. I've reviewed the transcript
10 from Hecht. That was very good. I enjoyed
11 reading that and had some critical
12 understanding of that. Raphael Nudelman as
13 well, and Panigrahy. Those are the ones that
14 come to the forefront of my memory, but I've
15 read other ones as well.
16 Q. Did you read all of them?
17 A. I opened all of them, but I
18 read in detail the ones relevant to my area
19 of expertise.
20 Q. On the -- when you say you
21 opened them, what does that mean?
22 A. They were provided as PDFs, and
23 I clicked open, and I would look through, see
24 the topic. If it was not relevant to my

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1 report and my level of expertise, my area of
2 expertise, then I would go on to another one.
3 Q. Did you add to your report
4 critiques of the deposition testimony that
5 you read?
6 A. I think my critiques were on
7 the expert reports and not on the expert
8 depositions, mainly due to timings of the
9 report, because the depositions hadn't
10 appeared at that time. So I was critiquing
11 the reports and reflecting on that within my
12 report. That's my understanding.
13 Q. Did you create any writings
14 regarding your critiques of the deposition
15 testimony?
16 A. I did not.
17 Q. Did you make any notes
18 regarding your review of the deposition
19 testimonies that you read?
20 A. I did not. My practice with
21 this, observe comments and statements within
22 the depositions that I agree with sometimes,
23 and I think that's useful information to
24 remember. If I disagree with it, I'll look

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1 into it, I'll research it by reading the
2 up-to-date scientific knowledge around that
3 topic, and come to my own understanding of
4 whether I agree with that statement or not,
5 with no notes. Just into my -- into my
6 brain.
7 Q. Now, you mentioned that you
8 reviewed Raphael Nudelman's deposition?
9 A. Yes. And I think that was --
10 we had feedback then. I think that was quite
11 an early one, if I remember correctly.
12 Q. Do you know Raphael Nudelman?
13 A. I have met Raphael Nudelman.
14 Should I tell the story of how I know him?
15 No?
16 MS. LOCKARD: Just answer the
17 question, Dr. Johnson. Listen to the
18 question and answer the question,
19 please.
20 A. I do know Raphael Nudelman.
21 Since this issue started, I've met him since
22 that time.
23 BY MS. BOGDAN:
24 Q. How did you first become

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1 acquainted with Raphael Nudelman?
2 A. I had looked into this topic on
3 my own regard with some of my regulatory
4 colleagues. I've prepared a PowerPoint
5 presentation, and I've been invited to
6 present this at an Informa Impurities
7 conference in Berlin, and at that time I met
8 Raphael Nudelman, I think over breakfast, and
9 I saw his -- he'd seen my presentation, he
10 was interested in my presentation, and I met
11 him at that time.
12 [REDACTED]
13 [REDACTED]
14 [REDACTED]
15 [REDACTED]
16 [REDACTED]
17 [REDACTED]
18 [REDACTED]
19 [REDACTED]
20 [REDACTED]
21 [REDACTED]
22 [REDACTED]
23 [REDACTED]
24 [REDACTED]

Page 36

1 [REDACTED]
2 [REDACTED]
3 [REDACTED]
4 [REDACTED]
5 [REDACTED]
6 [REDACTED]
7 [REDACTED]
8 [REDACTED]
9 [REDACTED]
10 [REDACTED]
11 Q. Now, when you say colleagues,
12 I'm not looking for the private health
13 information with regard to whichever
14 individual was on valsartan, but who did you
15 speak with regarding this topic as far as
16 your interest in it and wanting to learn more
17 information about it?
18 A. So that small group that I
19 discussed, we were all -- we're all risk
20 assessment experts and genetic toxicology
21 experts and cancer bioassay experts. We
22 discussed it in depth with those colleagues.
23 I then opened it up to a group
24 that I chair within the Health Environmental

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1 Science Institute based in Washington, D.C.
2 that's a tripartite -- tripartite
3 organization made up of regulatory bodies of
4 industry, academics and consultants, and I
5 presented it to that group.
6 And we -- and they -- I was
7 doing the work. They were interested. They
8 were helping with the adjustment factors
9 within the PDE, critiquing it. I presented
10 at Impurities conferences, which were made up
11 of the same sort of people, industry,
12 regulatory experts and so on.
13 And at that time, I had not
14 been to many Impurities conferences, but
15 since this was so relevant, I started getting
16 invited to a lot of Impurities conferences,
17 and at those times I was learning from the
18 other speakers as well from their
19 presentations, it was very good. I was
20 becoming very up to date with the topic, and
21 yeah, lots and lots of people.
22 This is my area of research for
23 the last few years independently of this
24 case, and I work with many different expert

<p style="text-align: right;">Page 38</p> <p>1 groups where this relates to our interest.</p> <p>2 Q. Now, what were the names of --</p> <p>3 you mentioned that there were several</p> <p>4 Health Canada colleagues that you spoke with.</p> <p>5 Who are they?</p> <p>6 A. That's a confidential matter as</p> <p>7 far as I'm concerned.</p> <p>8 Q. The names of the Health Canada</p> <p>9 colleagues that you spoke with regarding the</p> <p>10 issue with nitrosamine contamination in</p> <p>11 valsartan?</p> <p>12 A. Yes.</p> <p>13 Q. Why do you say that that's a</p> <p>14 confidential...</p> <p>15 A. Because of the nature of this</p> <p>16 case.</p> <p>17 MS. BOGDAN: I don't understand</p> <p>18 what privilege the witness is</p> <p>19 claiming. If he had conversations</p> <p>20 regarding this issue on the topic of</p> <p>21 nitrosamine contamination --</p> <p>22 MS. LOCKARD: His position --</p> <p>23 MS. BOGDAN: -- I just want to</p> <p>24 know --</p>	<p style="text-align: right;">Page 40</p> <p>1 is not public information, and, you</p> <p>2 know, the identities of these</p> <p>3 individuals from the Health Canada</p> <p>4 agency would be relevant, highly</p> <p>5 pertinent and certainly discoverable.</p> <p>6 BY MS. BOGDAN:</p> <p>7 Q. Do you serve with any of these</p> <p>8 individuals in -- on any of the groups or</p> <p>9 committees that you've referenced in your</p> <p>10 earlier testimony?</p> <p>11 A. That is correct. I work with</p> <p>12 some of these regulatory experts on sort of</p> <p>13 these expert groups.</p> <p>14 Q. And which expert groups do you</p> <p>15 serve with these individuals on?</p> <p>16 A. We've created with the experts</p> <p>17 on the question -- apologies. Wipe that.</p> <p>18 That didn't make sense.</p> <p>19 I work with many of these</p> <p>20 experts on the Health Environmental Science</p> <p>21 Institute Genetic Toxicology Technical</p> <p>22 Committee, the HESI GTTC, and also on the</p> <p>23 upcoming IWGT, I think the expanded version</p> <p>24 of that is the International Workshop on</p>
<p style="text-align: right;">Page 39</p> <p>1 MS. LOCKARD: Yeah, his</p> <p>2 position on this is that he had</p> <p>3 discussions confidentially prior to</p> <p>4 being retained in this case with these</p> <p>5 agency individuals, and that</p> <p>6 discussion occurred with the</p> <p>7 understanding that it was</p> <p>8 confidential. So he's uncomfortable</p> <p>9 disclosing those names.</p> <p>10 MS. BOGDAN: Well, I --</p> <p>11 MS. LOCKARD: So I'll make an</p> <p>12 objection based on confidentiality,</p> <p>13 and, you know, if we need to discuss</p> <p>14 it off the record, we can do that.</p> <p>15 THE WITNESS: That's correct,</p> <p>16 that is my position.</p> <p>17 MS. BOGDAN: Well, it will be</p> <p>18 the plaintiffs' position that with</p> <p>19 regard to anyone that he spoke with</p> <p>20 particularly regarding this issue at</p> <p>21 the time that the recall became known,</p> <p>22 that that would be highly relevant to</p> <p>23 the issues posed here in this matter.</p> <p>24 And certainly this deposition</p>	<p style="text-align: right;">Page 41</p> <p>1 Genetic Toxicology, and it's upcoming. It's</p> <p>2 supposed to be this year in Ottawa, and it's</p> <p>3 been delayed due to COVID to be next year.</p> <p>4 MS. BOGDAN: If we could pull</p> <p>5 up the 2020 HESI Annual Report,</p> <p>6 please.</p> <p>7 MS. LOCKARD: You'll have to</p> <p>8 use your link for that.</p> <p>9 THE WITNESS: I'm just going to</p> <p>10 find it now on the Golkow.</p> <p>11 (Whereupon, Deposition Exhibit</p> <p>12 Johnson-3, 2020 HESI Annual Report,</p> <p>13 was marked for identification.)</p> <p>14 THE WITNESS: It has yet to</p> <p>15 appear on it, on Golkow.</p> <p>16 MS. LOCKARD: Hit refresh.</p> <p>17 THE WITNESS: I'm refreshing.</p> <p>18 Exhibit 3, is that correct?</p> <p>19 TRIAL TECHNICIAN: That is</p> <p>20 correct.</p> <p>21 THE WITNESS: Thank you.</p> <p>22 BY MS. BOGDAN:</p> <p>23 Q. Is this the organization that</p> <p>24 you were referring to, Dr. Johnson?</p>

<p style="text-align: right;">Page 42</p> <p>1 A. I need a few seconds while the 2 slow Internet catches up. It's still 3 loading. 4 Q. Okay. 5 A. HESI Annual Report. Correct. 6 A subset of HESI. They're made up of 7 different expert groups, and the GTTC is one 8 such group. 9 Q. What is HESI? 10 A. I've stated it in previous 11 questions and I'll state it again. It's the 12 Health Environmental Science Institute. 13 Q. What is its purpose? 14 A. My way of describing them is we 15 find best practice or we find issues that 16 relate to our expertise or we find blue-sky 17 thinking of new approaches. We create an 18 expert group, we critique that, and then we 19 publish that and ensure the publish size and 20 keep it all open. And then we educate as 21 well through workshops and publications. 22 Q. What are the funding sources 23 for HESI? 24 A. As a whole, they are -- so</p>	<p style="text-align: right;">Page 44</p> <p>1 funding platform is. 2 Q. Are you an employee of HESI? 3 A. No. They do not pay me in any 4 way. They pay for the meetings, but there's 5 been no meetings since COVID. There's been 6 online meeting technologies that may have 7 cost some of the money, but the face-to-face 8 meetings uses up the major proportion of 9 that, and then some of the rest of the 10 funding goes towards funding HESI staff to 11 support our clerical needs. There's no money 12 that goes to me. 13 Q. Does HESI fund research? 14 A. They have an ability to fund 15 research. Those subgroups have an ability to 16 use money, if there's surplus money, to fund 17 research. It's not -- it's up to that 18 committee. 19 Q. Have you done any research that 20 was funded by HESI? 21 A. Not that I'm aware of. The 22 reason for my delay is we've had funding -- 23 it's usually been from Health Canada -- to 24 support our project, and then we integrate</p>
<p style="text-align: right;">Page 43</p> <p>1 industry provides funds across the different 2 industry bodies to HESI, and then there's 3 subsets of that. A portion of funding goes 4 to the expert groups, and those expert groups 5 can use the funding for meetings. 6 Q. And when you say industry, what 7 types of industries are you referring to? 8 A. It includes pharmaceutical 9 companies, also contract research 10 organizations, also -- I think we still have 11 cosmetics companies, agrochemical companies, 12 pet- -- not petrochemical companies at the 13 current time, I do not think, but that may be 14 incorrect. 15 So anyone that uses genetic 16 toxicology within their day-to-day life. If 17 there's a big company involved within that, 18 then they would want to be a part of this 19 expert committee. 20 Q. So HESI is funded by industry, 21 which would be made up of pharmaceutical 22 companies, chemical companies and other 23 business entities? 24 A. That's how I understand their</p>	<p style="text-align: right;">Page 45</p> <p>1 that within the HESI group. So that's how I 2 see it. 3 So we do projects within our 4 group, and then they're always funded by 5 Health Canada. 6 And if there's an example where 7 I have been funded for HESI research, that 8 would be my misunderstanding that it would 9 be -- I think it's Health Canada. 10 My confident answer is no. 11 Q. And -- 12 A. Apologies. I would definitely 13 not be the PI if that was the case anyway. 14 Sorry. 15 Q. And when you say PI, are you 16 referring to principal investigator? 17 A. Exactly that term. 18 Q. So which of the committees are 19 you affiliated with with HESI? Would that be 20 the genetic toxicology group? 21 A. Yes, that would be the one. 22 Q. And what role do you have with 23 the genetic toxicology group? 24 A. There's a subgroup called the</p>

<p style="text-align: right;">Page 46</p> <p>1 quantitative subgroup, where we address 2 exactly the issue we're discussing today, and 3 I chair that. I cochair that with another 4 member. He's currently from 5 Hoffman-La Roche, Andreas Zeller, and 6 previously it was someone from Health Canada. 7 And yeah, it's usually -- so that's my role 8 within there.</p> <p>9 And when you're a chair of a 10 subgroup, you become on the steering group of 11 the GTTC.</p> <p>12 Q. And GCC [sic] stands for? 13 A. GTTC stands for Genetic 14 Toxicology Technical Committee, as far as I'm 15 aware.</p> <p>16 Q. So for the transcript, that 17 should be GTTC, correct -- 18 A. Correct.</p> <p>19 Q. -- not GCC? Okay, that makes 20 sense.</p> <p>21 A. Cool.</p> <p>22 Q. And who is on the subgroup with 23 you? 24 A. It's a big subgroup. There's</p>	<p style="text-align: right;">Page 48</p> <p>1 requested for that. The consultants, the 2 academics and the regulatory bodies are not 3 requested that funding, as far as I'm aware.</p> <p>4 Q. What is the cost for an 5 industry -- when you say industry group, are 6 you referring to individual companies? 7 A. I am referring to individual 8 companies.</p> <p>9 Q. And what is the fee for an 10 individual company to join HESI in a given 11 year? 12 A. I do not want to say an 13 incorrect number. Because I'm not a company, 14 I don't know the exact number.</p> <p>15 Q. If we could move to page 33 of 16 this exhibit, which should have Genetic 17 Toxicology. And when I say 33, I mean the 18 numbered page 33. There we go.</p> <p>19 A. I'm almost there.</p> <p>20 Q. And, Doctor, let me know once 21 you have that loaded on the screen.</p> <p>22 A. With the top word being 23 "Genetic Toxicology" and then "Our Mission"; 24 is that correct?</p>
<p style="text-align: right;">Page 47</p> <p>1 different levels of membership. There's 2 interested parties, and that includes many 3 regulators, many industry experts, many 4 academics, many consultants. Then there's an 5 active -- more active work group, that would 6 include myself, Paul White from Health 7 Canada, and Andreas Zeller, and we do a large 8 proportion of the work and present that to 9 the wider group, who are very interested in 10 this topic and have opinions but have less 11 time to put into it because this is our 12 research area of expertise.</p> <p>13 Q. Now, does this organization 14 collect committee dues? Are there dues that 15 people have to pay to belong? 16 A. My understanding of the funding 17 is the HESI bigger committee takes an annual 18 fee from the company, and then they pay a 19 certain amount to become a part of a group 20 such as the GTTC. That's my understanding of 21 the funding.</p> <p>22 Q. So the members pay a fee to 23 HESI to belong to the organization? 24 A. The industry groups are</p>	<p style="text-align: right;">Page 49</p> <p>1 Q. Yes.</p> <p>2 A. Excellent. Thank you. I have 3 that in front of me.</p> <p>4 Q. Okay. Is that the group to 5 which you belong? 6 A. Yes.</p> <p>7 Q. And then if we could move to 8 page 35, please.</p> <p>9 A. Yeah, I can see that too.</p> <p>10 Q. Okay. Great.</p> <p>11 Under In Progress at the top of 12 the page, in the third sentence, could you 13 read that, please, beginning with 14 "Permitted"? 15 A. Permitted daily exposure limits 16 for noteworthy mutagenic nitrosamines. And 17 this entirely links to my publication, which 18 was a HESI publication.</p> <p>19 Q. And when you say links to, so 20 this is referencing a publication that you 21 were actually involved with, correct? 22 A. Correct.</p> <p>23 Q. And when was that publication 24 published?</p>

<p style="text-align: right;">Page 50</p> <p>1 A. I'm reaching to get it because 2 the exact date could be useful. It was 3 received 1st of March 2021 and accepted 11th 4 of May 2021. 5 Q. So that was actually 6 referencing that publication that you had 7 underway in 2020? 8 A. Yes, and as I mentioned 9 previously, it was underway at the time of my 10 presentation in Berlin too, just the research 11 around it. 12 Q. And are you referring to the 13 2018 presentation in Berlin? 14 A. Correct. 15 Q. And who did you attend -- or 16 you actually spoke at the 2018 -- 17 A. I think -- 18 Q. -- Berlin presentation or did 19 you just attend? 20 (Clarification requested by the 21 stenographer.) 22 THE WITNESS: Berlin Informa. 23 BY MS. BOGDAN: 24 Q. And what was the name of that</p>	<p style="text-align: right;">Page 52</p> <p>1 know who the leading experts in that area 2 were. 3 Q. And who did Raphael Nudelman 4 work for at the time, if anyone, in 2018 when 5 you first met him? 6 A. It was my understanding that he 7 worked for Teva. 8 Q. Does he still work for Teva, to 9 your understanding? 10 A. I think he does, yes. I'm 11 confident that he does. 12 Q. And Andrew Teasdale, what 13 company does he work for? 14 A. He works for AstraZeneca, and 15 he's on many, many expert groups on this 16 topic. 17 Q. And what prompted the holding 18 of this conference in Berlin in 2018? 19 MS. LOCKARD: Objection, form, 20 speculation. 21 You can answer. 22 THE WITNESS: I can answer? 23 A. Informa, from my recollection 24 and understanding, have been running</p>
<p style="text-align: right;">Page 51</p> <p>1 seminar? 2 A. I've attended many seminars. 3 The Informa seminars would have Informa 4 Impurities. The focus is on impurities 5 within that seminar. 6 Q. Who was the sponsor of that 7 seminar? 8 A. I do not know. Informa were 9 the people running it. 10 Q. Is Informa the name of the 11 company or the administrative group that runs 12 seminars? 13 A. My understanding is the 14 administrative group that runs seminars. 15 Q. Who spoke with you at that 16 seminar? 17 A. I cannot recall exactly. My 18 answer would be that's where I met Raphael 19 Nudelman, as I've previously stated in my 20 dep, due to a previous question; and Andrew 21 Teasdale presented as well. He's a leading 22 expert in impurities. And beyond that, I 23 couldn't recall any other names. That was my 24 first Impurities conference, and I was yet to</p>	<p style="text-align: right;">Page 53</p> <p>1 Impurities conferences for many years, and as 2 an expert, as a group of scientists and 3 people working on topics, you always present 4 the newest topic under consideration at that 5 time. So that would have been the reason for 6 detailing on this topic. 7 BY MS. BOGDAN: 8 Q. Had the recalls or the issue 9 with nitrosamine contamination in valsartan 10 come to the forefront before this meeting 11 took place? 12 MS. LOCKARD: Objection, 13 compound, vague. 14 A. I'm unaware of that. 15 BY MS. BOGDAN: 16 Q. Were valsartan recalls part of 17 the topic that was addressed at this Berlin 18 conference in 2018? 19 A. The topic, potentially, 20 instructions would mention the reason for our 21 focus on this topic. The science was the 22 focus of the topic. It was mostly to do with 23 the structural activity relationship experts, 24 so I was in the room for the chemists talking</p>

<p>Page 54</p> <p>1 about chemistry, and I was the toxicologist. 2 So we talked about the science, but there 3 would have been introductory information as 4 well. 5 Q. Did this conference take place 6 after it became known that NDMA was in 7 valsartan? 8 MS. LOCKARD: Objection, form, 9 vague. 10 A. My understanding -- I do not 11 know the answer to that. 12 BY MS. BOGDAN: 13 Q. What did you speak on at this 14 conference? 15 A. It was very similar to my 16 publication and aspects of my report, which 17 is more detailed and focused risk assessment 18 of this exploratory paper. 19 So it was on the first steps in 20 producing the paper, so it was to show that 21 NDMA, and potentially I think I talked to 22 NDEA at that time, were mutagenic substances 23 with very clear mutation spectrum, with very 24 clear DNA adducts, with very clear</p> <p>Page 55</p> <p>1 understanding about DNA repair, and that's 2 been my area of expertise for many years. 3 So I introduced that in some 4 slides, and then I showed with that 5 understanding you can carry out permitted 6 daily exposure according to the ICH guidance, 7 and I carried out a permitted daily exposure 8 with some of the data available to me. 9 Q. Did this conference take place 10 in June of 2018? 11 A. Potentially. 12 Q. And when was the conference 13 originally scheduled to take place, as far -- 14 excuse me. 15 When was the date of the 16 conference set? 17 A. I do not know. 18 Q. When were you invited to speak 19 at the conference? 20 A. I do not know. 21 Q. Were you invited to speak at 22 the conference more than a month before it 23 took place? 24 A. I do not know. I've presented</p>	<p>Page 56</p> <p>1 at many of these conferences. 2 Q. Do you have any -- did you 3 present any written materials at the 4 conference? 5 A. I presented a slide set which I 6 spoke to. 7 Q. So a PowerPoint-type 8 presentation? 9 A. Yes. 10 Q. Do you still have that? 11 A. I'm unaware if I do. 12 Q. Did anyone at the conference 13 speak specifically about NDMA or NDEA in 14 valsartan? 15 A. Andrew Teasdale presented the 16 issue at hand and the reason, the chemical 17 reason for NDMA in this instance. 18 Q. And who does Andrew Teasdale -- 19 or who did he work for at the time? 20 MS. LOCKARD: Objection, asked 21 and answered. 22 MS. BOGDAN: I remember the 23 doctor saying Raphael Nudelman worked 24 for Teva.</p> <p>Page 57</p> <p>1 BY MS. BOGDAN: 2 Q. Who did Andrew Teasdale work 3 for? 4 MS. LOCKARD: Objection, asked 5 and answered. 6 A. As stated previously, Andrew 7 Teasdale works for AstraZeneca and did at 8 that time, and he's also party to numerous 9 expert groups, including the official ones 10 which talk with the regulatory bodies. 11 BY MS. BOGDAN: 12 Q. How many speakers presented at 13 this conference in Berlin? 14 A. I do not know. 15 Q. Was it one day of presentations 16 or more than one day? 17 A. I do not know. At an estimate, 18 two days. 19 Q. Did you go with anyone to the 20 conference? 21 A. No, I did not. I went to 22 Berlin by myself. It was exciting. 23 Q. If we could go back to the 24 exhibit, same page, 35.</p>
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<p style="text-align: right;">Page 58</p> <p>1 A. This was the HESI document?</p> <p>2 Q. Yes.</p> <p>3 A. Okay.</p> <p>4 Q. And if we could go to</p> <p>5 Participating Organizations.</p> <p>6 A. Participate -- on page 35?</p> <p>7 Q. Yeah. And if we could go to</p> <p>8 Academic/Research Institutes.</p> <p>9 A. Yep. I'm there, yes.</p> <p>10 Q. Is the university that you work</p> <p>11 for listed?</p> <p>12 A. Yes. I work for Swansea</p> <p>13 University.</p> <p>14 Q. And how long have you worked</p> <p>15 for Swansea?</p> <p>16 A. I carried out my Ph.D. from</p> <p>17 2002 to 2006, at which time I did some</p> <p>18 demonstrating, so I think I got paid at that</p> <p>19 time. The 2007 period, I had a postdoctoral</p> <p>20 research project on dose response in another</p> <p>21 set of compounds that were not nitrosamines.</p> <p>22 Then I got a job as a tutor,</p> <p>23 which is a teaching role, and I had research</p> <p>24 ability at that time. And then I worked my</p>	<p style="text-align: right;">Page 60</p> <p>1 affiliated with the Genetic Toxicology</p> <p>2 Committee?</p> <p>3 A. Yes, correct.</p> <p>4 Q. Could you please read the names</p> <p>5 of the companies and tell me what type of</p> <p>6 business they're in?</p> <p>7 MS. LOCKARD: Objection.</p> <p>8 BY MS. BOGDAN:</p> <p>9 Q. If you know.</p> <p>10 MS. LOCKARD: Vague.</p> <p>11 BY MS. BOGDAN:</p> <p>12 Q. Well, we can go one by one</p> <p>13 then. The first company listed is AbbVie.</p> <p>14 Do you see that?</p> <p>15 A. I see AbbVie. I --</p> <p>16 Q. What is -- what is the business</p> <p>17 of AbbVie?</p> <p>18 A. I do not know. I think they</p> <p>19 may have a pharmaceutical wing, but I'm not</p> <p>20 confident in that statement.</p> <p>21 Q. The next company is Amgen.</p> <p>22 Do you see that?</p> <p>23 A. I see that, and it would be the</p> <p>24 same answer. They may have a pharmaceutical</p>
<p style="text-align: right;">Page 59</p> <p>1 way through the grades to where I am today.</p> <p>2 So that's the time -- the time</p> <p>3 frame.</p> <p>4 Q. And when you say worked my way</p> <p>5 through the grades to where I am today, where</p> <p>6 are you today?</p> <p>7 A. I'm an associate professor;</p> <p>8 that's one down from professor in the</p> <p>9 university -- in the U.K. university career</p> <p>10 grades.</p> <p>11 Q. Are you on track to become a</p> <p>12 professor?</p> <p>13 A. Yes, very close to becoming</p> <p>14 professor.</p> <p>15 Q. If we could go back to page 35</p> <p>16 and look at Industry, please, which is right</p> <p>17 under Academic/Research Institutions?</p> <p>18 A. Not that I am looking -- I'm</p> <p>19 not looking at Zoom, but I have it in front</p> <p>20 of me. Thank you.</p> <p>21 Q. And do you recognize the names</p> <p>22 of the companies listed?</p> <p>23 A. I do recognize them, yes.</p> <p>24 Q. And this list of companies is</p>	<p style="text-align: right;">Page 61</p> <p>1 wing, but I do not know.</p> <p>2 Q. Do you know any other type of</p> <p>3 business Amgen is involved in?</p> <p>4 A. I -- I do not, no.</p> <p>5 Q. Are they a chemical company?</p> <p>6 A. I repeat myself. I do not</p> <p>7 know.</p> <p>8 Q. The next company name,</p> <p>9 AstraZeneca, what type of company is</p> <p>10 AstraZeneca?</p> <p>11 A. Pharmaceutical company.</p> <p>12 Q. The next company, BASF, what</p> <p>13 type of business do they have?</p> <p>14 A. Chemical company.</p> <p>15 Q. The next company, Boehringer</p> <p>16 Ingelheim, what type of company is that?</p> <p>17 MS. LOCKARD: Objection, vague.</p> <p>18 BY MS. BOGDAN:</p> <p>19 Q. What is the business of</p> <p>20 Boehringer Ingelheim?</p> <p>21 A. I know -- I think they have a</p> <p>22 pharmaceutical wing and they may do other</p> <p>23 business as well.</p> <p>24 Q. The next company, Bristol Myers</p>

<p style="text-align: right;">Page 62</p> <p>1 Squibb Company, what is their business, if 2 you know? 3 A. Again, I think they have a 4 pharmaceutical wing and a focus on 5 pharmaceuticals. I'm unaware of their other 6 business. 7 Q. The next company listed, 8 Charles River Laboratories. What is the 9 business of Charles River Laboratories? 10 A. Charles River are a leading 11 contract research organization to which 12 industry and government regulatory bodies get 13 a lot of their work carried out, so lots of 14 the genetic toxicology-type approaches and 15 cancer bioassays. 16 Q. And they actually do testing 17 and laboratory-type work? 18 A. Correct, on a very large scale. 19 Q. The next company, Corteva 20 Agriscience, what is the business of Corteva 21 Agriscience? 22 A. I do not know, but from the 23 second word, I would assume some agrochemical 24 links.</p>	<p style="text-align: right;">Page 64</p> <p>1 A. The Dow Chemical Company are a 2 chemical company. 3 Q. Yeah. 4 The next company listed, Eli 5 Lilly and Company, what is the business of 6 Eli Lilly? 7 A. I think, again, that they have 8 a pharmaceutical wing and some focus, and 9 potentially they'll do other business. 10 That's -- that's my understanding. 11 Q. The next company, Genentech, 12 what is the business of Genentech? 13 A. Again, I don't have a clear 14 understanding of their -- of their work. 15 Q. The next company, Gentronix, 16 what is the work of Gentronix? 17 A. Gentronix are an up-and-coming 18 contract research organization, and in 19 addition to carrying out the CRO work, the 20 contract research organization work, for 21 industry, and also for regulatory bodies and 22 so on, and government research bodies and all 23 those guys, they also have some inventions of 24 their own test systems too.</p>
<p style="text-align: right;">Page 63</p> <p>1 Q. Covance, do you see that 2 company listed? 3 A. I do. I see -- apologies. 4 Q. No, we just have a little bit 5 of delay. I apologize as well. I'm not 6 trying to speak over you, and I know you're 7 not trying to speak over me. 8 What is the business of 9 Covance? 10 A. Covance are in the same 11 industrial field as Charles River and carry 12 out a lot of the genetic toxicology, cancer 13 bioassay work and clinical trials work for 14 everyone, including industry and regulatory 15 bodies and academics, if they wish. It's a 16 contract research organization. 17 Q. The next company, Denali 18 Therapeutics, what is the business of Denali? 19 A. I do not know Denali, but from 20 therapeutics, they should be in the business 21 of therapeutics. 22 Q. The next company, the Dow 23 Chemical Company, what is the business of Dow 24 Chemical Company?</p>	<p style="text-align: right;">Page 65</p> <p>1 Q. The next company listed, 2 GlaxoSmithKline, what is the business of 3 GlaxoSmithKline? 4 A. I'm confident that they have a 5 pharmaceutical wing and they change their 6 profiles quite a lot, but used to make some 7 food as well, I think. 8 Q. The next entity, Helix3 Inc., 9 what is the business of Helix3 Inc.? 10 A. From my understanding, I think 11 they're a contract research organization, 12 again, a small one, using novel approaches, 13 but again, doing this work for industry and 14 for government regulatory bodies and anyone 15 such as NIH who wishes to outsource any 16 experimental work. 17 Q. The next company, Janssen 18 Pharmaceuticals, is that a pharmaceutical 19 company to your knowledge? 20 A. Janssen Pharmaceuticals is a 21 subset of Johnson & Johnson, and this is 22 their pharmaceutical wing. 23 Q. The next company, Litron 24 Laboratories, are you familiar with that</p>

<p style="text-align: right;">Page 66</p> <p>1 company?</p> <p>2 A. Yes, very familiar with Litron</p> <p>3 Laboratories. You'll see from my</p> <p>4 publications, I work with them on science a</p> <p>5 lot. They are a CRO, contract research</p> <p>6 organization, and they also carry out a lot</p> <p>7 of inventive, patented assay development</p> <p>8 work, and they're very well regarded as well.</p> <p>9 So again, a CRO.</p> <p>10 Q. When you say a contract</p> <p>11 research organization, that means they can be</p> <p>12 contracted by a third party to do research,</p> <p>13 correct?</p> <p>14 A. They can, but usually it's less</p> <p>15 research and more mandated assays, including</p> <p>16 the genetic toxicology assays that would go</p> <p>17 towards submissions or to hazard and risk</p> <p>18 assessments by the regulatory body</p> <p>19 themselves.</p> <p>20 Q. So they do more testing?</p> <p>21 A. Contract research organization,</p> <p>22 the focus would be on testing, and the</p> <p>23 companies and regulatory bodies would</p> <p>24 outsource that work for these bodies to do</p>	<p style="text-align: right;">Page 68</p> <p>1 laboratory research to buy consumables and so</p> <p>2 on for tissue culture and buy the chemicals</p> <p>3 for the testing. They're such a big company,</p> <p>4 they may have other wings as well, but from</p> <p>5 my understanding of Sigma is they produce a</p> <p>6 lot of scientific reagents.</p> <p>7 Q. And the next company, Novartis,</p> <p>8 what is the business of Novartis?</p> <p>9 A. Novartis, I'm quite confident</p> <p>10 they're focused on pharmaceuticals entirely,</p> <p>11 I think.</p> <p>12 Q. The next company, Pfizer Inc.,</p> <p>13 what's the business of Pfizer?</p> <p>14 A. Again, Pfizer are a very large</p> <p>15 pharmaceutical company.</p> <p>16 Q. The next company listed is</p> <p>17 Procter & Gamble Company. What is the</p> <p>18 business of Procter & Gamble?</p> <p>19 A. My understanding of Procter &</p> <p>20 Gamble is the focus is on cosmetics, and I</p> <p>21 think they've got some food and</p> <p>22 nutraceuticals and products along those</p> <p>23 lines, but I don't think there's a focus on</p> <p>24 pharmaceuticals as such.</p>
<p style="text-align: right;">Page 67</p> <p>1 their testing, all in accordance with OECD</p> <p>2 guidelines.</p> <p>3 Q. The next company, L'Oreal</p> <p>4 Corporation, is that -- (audio</p> <p>5 malfunction) --</p> <p>6 (Clarification requested by the</p> <p>7 stenographer.)</p> <p>8 BY MS. BOGDAN:</p> <p>9 Q. Is that a cosmetic company?</p> <p>10 A. According to my understanding,</p> <p>11 they focus on cosmetics.</p> <p>12 Q. The next company, Merck &</p> <p>13 Company, what is the business of Merck?</p> <p>14 A. I would like to take this one</p> <p>15 and the next one together. I'm aware that</p> <p>16 there's two Mercks, and I think they both</p> <p>17 have a focus on pharmaceuticals. And one is</p> <p>18 more European and one is more American, and I</p> <p>19 don't know which one is which.</p> <p>20 Q. The next company,</p> <p>21 MilliporeSigma, what is the business of</p> <p>22 MilliporeSigma?</p> <p>23 A. MilliporeSigma are a huge</p> <p>24 company. They -- we use them a lot in</p>	<p style="text-align: right;">Page 69</p> <p>1 Q. The next company listed, Roche,</p> <p>2 what is the business of Roche?</p> <p>3 A. Roche are a pharmaceutical</p> <p>4 company, and I think they produce equipment</p> <p>5 as well for research, such as PCRs and such.</p> <p>6 Q. The next company, Sanofi, what</p> <p>7 is the business of Sanofi?</p> <p>8 A. I think they're a</p> <p>9 pharmaceutical company.</p> <p>10 Q. And the next company, Syngenta,</p> <p>11 what is the business of Syngenta?</p> <p>12 A. I think they're an agrochemical</p> <p>13 company, but I may need to be corrected.</p> <p>14 Q. The next company, Takeda</p> <p>15 Pharmaceutical Company, is that a</p> <p>16 pharmaceutical company?</p> <p>17 A. Apologies for talking over you.</p> <p>18 I think they are a Japanese</p> <p>19 pharmaceutical company.</p> <p>20 Q. And then lastly, Toxys, what is</p> <p>21 the business of Toxys?</p> <p>22 A. Contract research organization.</p> <p>23 I would compare them with Gentronix, Litron.</p> <p>24 A new contract research organization that</p>

<p style="text-align: right;">Page 70</p> <p>1 comes up with novel assays that they've 2 patented, so that kind of work. Contract 3 research organization and inventors and 4 sellers of their products. 5 Q. Now, do each of these 6 industries that we've gone through elect to 7 be affiliated with the genetic toxicology 8 committee? 9 A. My understanding is, is that's 10 correct, but they will not be a part of all 11 of the different subgroups. 12 Q. Do they have representatives 13 that serve on the genetic toxicology 14 committee? 15 A. They do, but not all of them on 16 the quantitative group to which this work is 17 focused. 18 Q. Which of these companies have 19 committee members on the quantitative 20 subcommittee group? 21 A. The most precise way for this 22 answer would be the list of coauthors on my 23 publication in May 2021 titled Permitted 24 Daily Exposure -- Daily Exposure Limits for</p>	<p style="text-align: right;">Page 72</p> <p>1 work. 2 Q. Are all of the individuals that 3 have an active role in this work coauthors? 4 A. Yes, that's my understanding of 5 that, yes. 6 Q. So who are those individuals 7 that serve on the quantitative subcommittee 8 group with you? 9 A. We have the people on my paper. 10 Myself and Andreas chair the group, and Paul 11 White is an active member. He was cochair, 12 but due to workload, has now stepped back. 13 But he's in a leadership position with myself 14 and Andreas Zeller. 15 And then depending on the 16 project, people will come in or not to be an 17 active participant in the next publication. 18 For example, the next one is being created by 19 Health Canada to carry out risk assessments 20 using confidence intervals for -- from BMD 21 for mutation and cancer, and that will be 22 directed -- I think the next two papers are 23 Health Canada-focused projects that will have 24 an expanded list of authors who will</p>
<p style="text-align: right;">Page 71</p> <p>1 Noteworthy N-nitrosamines. There's a list 2 there. Would you like me to read those? 3 Q. Are all of the coauthors on the 4 Permitted Daily Exposure Limits for 5 Noteworthy N-nitrosamines on the quantitative 6 subcommittee with you? 7 A. Yes, they were active members 8 on this publication, which is a part of the 9 quantitative subgroup's output. 10 Q. Okay. Was there -- were there 11 any members on the quantitative subcommittee 12 that were not coauthors of the Permitted 13 Daily Exposure Limits for Noteworthy 14 Nitrosamines article? 15 A. There would be. As I was 16 mentioning, there's an active group and then 17 there's a group of people who are keeping 18 updated. 19 So this would be the active 20 group, and then there would be the people 21 with interest in the topic as a larger body 22 of that group. So those would not be 23 coauthors on these. There's people that have 24 an interest but have no active role in this</p>	<p style="text-align: right;">Page 73</p> <p>1 contribute to that manuscript. 2 So it's a bit fluid depending 3 on which subproject, due to level of 4 expertise. These are very expert papers and 5 not everyone can contribute to a suitable 6 level. 7 Q. The ones that are coming out 8 that you mentioned were going to be 9 Health Canada-focused projects, are they 10 going to be dealing with nitrosamines? 11 A. They will not deal with 12 nitrosamines. A big area of interest for 13 that group is PAHs. 14 Q. Okay. Could you tell me the 15 names of the quantitative subcommittee 16 members that you serve with? I think you 17 said you were going to reference your 18 research article. 19 A. Yes. The members relevant to 20 today's discussion are entirely this subgroup 21 that actively worked on this nitrosamine 22 paper, and those are the names that I will 23 read now. 24 Shall I -- so Krista Dobo,</p>

<p style="text-align: right;">Page 74</p> <p>1 Bhaskar Gollapudi, Jim Harvey, Julia 2 Kenny, Michelle Kenyon, Anthony Lynch, Sheroy 3 Minocherhomji, John Nicolette, Veronique 4 Thybaud, Ryan Wheeldon, Andreas Zeller. 5 That's the complete list. 6 Q. And Krista Dobo, she works for 7 Pfizer, correct? 8 A. Yes, unless she's changed roles 9 recently, that would be correct. 10 Q. At the time that the work on 11 the article was underway, she worked for 12 Pfizer? 13 A. Yes. And to expand on that 14 question, each of these numbered affiliations 15 were correct and remain correct at this time. 16 Q. Meaning the numbers -- the 17 affiliations that are noted on the research 18 article itself? 19 A. Correct. 20 Q. So Bhaskar Gollapudi? 21 A. Bhaskar Gollapudi. 22 Q. Was affiliated with Exponent? 23 A. Correct. 24 Q. A consultant?</p>	<p style="text-align: right;">Page 76</p> <p>1 Q. Veronique Thybaud, affiliated 2 with Sanofi, correct? 3 A. Yes, that is correct. 4 Q. Okay. Ryan Wheeldon, or 5 Wheeldon or Wheeldon, he actually worked some 6 with you at the university? 7 A. That's correct. 8 Q. Does he work in your 9 department? 10 A. He is finishing up his Ph.D. 11 project with me. 12 Q. And then Andreas Zeller works 13 for Hoffman-La Roche, correct? 14 A. That is correct. And the 15 significance of him being last author is, as 16 I've mentioned previously, he cochairs this 17 group with me and has a very active role in 18 understanding this topic too. 19 Q. Now, you mentioned Paul White 20 had taken -- had an active role in this 21 Genetic Toxicology Committee at the time that 22 this research article was being worked on, 23 correct? 24 A. He did, yes. He focused on</p>
<p style="text-align: right;">Page 75</p> <p>1 A. Correct. 2 Q. Jim Harvey was affiliated with 3 GlaxoSmithKline, correct? 4 A. That is correct. 5 Q. Julia Kenny, also affiliated 6 with GlaxoSmithKline? 7 A. That is correct. 8 Q. Michelle Kenyon, affiliated 9 with Pfizer, as was Krista Dobo, correct? 10 A. That is correct. 11 Q. Anthony Lynch, also affiliated 12 with GlaxoSmithKline? 13 A. That is correct. 14 Q. Sheroy Minocherhomji, am I 15 pronouncing that correctly? 16 A. You're pronouncing it as well 17 as I can. 18 Q. Okay. Affiliated with Amgen? 19 A. According to -- I don't work 20 with him on a regular basis, but this is 21 correct information here, Amgen. 22 Q. John Nicolette, affiliated with 23 AbbVie, correct? 24 A. Yeah, correct.</p>	<p style="text-align: right;">Page 77</p> <p>1 other projects -- I think maybe three other 2 publications -- and therefore did not have 3 time to work on this project with us. 4 Q. Did he work on this project 5 with you at all? 6 A. He would have seen our 7 publications and discussed our work with us 8 with his expert understanding. So to that 9 extent, providing critique and so on. 10 Q. And when you say would have 11 seen our publications, meaning he would have 12 had input into the drafting of this article, 13 would have reviewed it before it was 14 published? 15 A. Not into the drafting, but the 16 output figures were presented to the Genetic 17 Toxicology Technical Committee, and at that 18 time, he would have discussed his opinions of 19 the topic at that time. 20 Q. And when you say output 21 figures, what are you referring to? 22 A. The dose-response modeling 23 within that publication. He's an expert on 24 BMD and will have had some opinions on that.</p>

<p style="text-align: right;">Page 78</p> <p>1 We wrote a paper together on adjustment 2 factors, and he had a good opinion on that. 3 Those main points. 4 Q. So his area of expertise is 5 dose-response modeling? 6 A. Yes. 7 Q. And I see here it's -- did you 8 say BMD or BND? 9 A. BMD, for which I'll mention 10 later, so I'll expand now, means benchmark 11 dose. So BMD, benchmark dose. 12 Q. But he is not a coauthor on the 13 paper, correct? 14 A. That is correct. 15 Q. Did you ask him to be a 16 coauthor on the paper? 17 A. We discussed it, but workload 18 issues, he didn't contribute to the 19 publication. 20 Q. And where does Mr. White work? 21 A. He works in Ottawa at 22 Health Canada and has a professorship at the 23 university there as well, at University of 24 Ottawa, I think.</p>	<p style="text-align: right;">Page 80</p> <p>1 MS. LOCKARD: It should come up 2 on both. 3 THE WITNESS: Okay. 4 MS. BOGDAN: If we could please 5 mark that as the next exhibit. 6 MS. LOCKARD: Exhibit 4. 7 THE WITNESS: I can see it on 8 Zoom, and I don't need to scroll, so 9 I'm happy. I can see it. 10 BY MS. BOGDAN: 11 Q. Is this the seminar or summit 12 that you were previously testifying about 13 that took place in Berlin in June of 2018? 14 A. As far as I'm aware, it is, but 15 I'm scanning for Informa, and cannot see 16 Informa on that slide. 17 Q. Okay. And that exhibit 18 indicates -- excuse me -- that it took place 19 on June 7th and 8th? 20 A. That exhibit does indicate 21 that, correct. 22 Q. And it took place at the 23 Mövenpick Hotel in Berlin. Is that where the 24 seminar took place?</p>
<p style="text-align: right;">Page 79</p> <p>1 MS. LOCKARD: We've been going 2 about an hour and a half, so when you 3 get to a good stopping point, can we 4 take a break? 5 MS. BOGDAN: Sure, we can take 6 a five-minute break right now if you'd 7 like. 8 MS. LOCKARD: Sure. 9 THE VIDEOGRAPHER: Going off 10 the record. The time is 10:35 a.m. 11 (Recess taken, 10:35 a.m. to 12 10:49 a.m. BST) 13 THE VIDEOGRAPHER: Back on the 14 record. The time is 10:49. 15 BY MS. BOGDAN: 16 Q. Could we pull up the exhibits 17 for the 2018 2nd Impurities seminar? 18 (Whereupon, Deposition Exhibit 19 Johnson-4, 2nd Impurities: Genotoxic 20 and Beyond Summit Slide, was marked 21 for identification.) 22 MS. LOCKARD: The 2018. 23 THE WITNESS: Will this appear 24 as Exhibit 4 or should I look at Zoom?</p>	<p style="text-align: right;">Page 81</p> <p>1 A. That's what it says on the 2 exhibit, correct. 3 Q. Okay. Is that where you 4 remember the seminar taking place in Berlin? 5 A. I remember it taking place in 6 Berlin. I can't recall the exact name of the 7 hotel. 8 Q. Okay. 9 MS. BOGDAN: If we could please 10 pull up the next exhibit and mark it 11 Exhibit 5, which would be the 12 presenters at the 2nd Impurity 13 genotoxic and beyond summit. 14 (Whereupon, Deposition Exhibit 15 Johnson-5, Speakers at 2018 Berlin 16 Summit, was marked for 17 identification.) 18 BY MS. BOGDAN: 19 Q. And please let me know once 20 that appears for you on the screen. 21 A. I can see this on Zoom, so it's 22 appearing on the screen, correct. 23 (Telephonic interruption.) 24 THE WITNESS: We have a phone</p>

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<p>1 call.</p> <p>2 MS. LOCKARD: False alarm.</p> <p>3 BY MS. BOGDAN:</p> <p>4 Q. Would you please look at that</p> <p>5 exhibit and tell me if those appear to be --</p> <p>6 well, first, let's see.</p> <p>7 Are you on that exhibit?</p> <p>8 A. Yes, I'm on that exhibit.</p> <p>9 Q. Okay. And do those appear to</p> <p>10 be the individuals that spoke at that 2018</p> <p>11 summit in Berlin?</p> <p>12 A. That appears to be correct, and</p> <p>13 triggered my memory that I didn't attend all</p> <p>14 of the lectures.</p> <p>15 Q. So you attended part of the</p> <p>16 seminar?</p> <p>17 A. Correct.</p> <p>18 Q. Which lectures, if you can</p> <p>19 remember, did you attend?</p> <p>20 A. I'm fairly confident I attended</p> <p>21 Andrew Teasdale's lecture. The rest, I</p> <p>22 potentially did not see. Definitely Andrew</p> <p>23 Teasdale.</p> <p>24 Q. Okay. Andrew Teasdale spoke</p>	<p>1 Q. So you know him as you sit here</p> <p>2 today, but you're not sure if you met him</p> <p>3 there?</p> <p>4 A. "Know him" is too strong. I'm</p> <p>5 aware of him and have been on these</p> <p>6 conferences at the same time as him.</p> <p>7 Q. And he works for GSK to your</p> <p>8 knowledge?</p> <p>9 A. To my knowledge, that's</p> <p>10 correct.</p> <p>11 Q. And Dr. Raphael Nudelman who is</p> <p>12 depicted there is the gentleman we've already</p> <p>13 spoken about who works for Teva, correct?</p> <p>14 A. That is correct.</p> <p>15 Q. How about Dr. Alexander Amberg</p> <p>16 with Sanofi, do you know that individual?</p> <p>17 A. I do not know that individual.</p> <p>18 Q. What about Lance Smallshaw with</p> <p>19 UCB Biopharma, do you know him?</p> <p>20 A. I do not know Lance Smallshaw.</p> <p>21 Q. How about Dr. Lutz Müller with</p> <p>22 Hoffman-La Roche?</p> <p>23 A. I do know him and have met him</p> <p>24 previous to this session. We worked together</p>
Page 83	Page 85
<p>1 about what?</p> <p>2 A. From my recollection, Andrew</p> <p>3 Teasdale spoke about how the chemistry, about</p> <p>4 how NDMA could be produced as an impurity in</p> <p>5 these drugs. That's what I recall.</p> <p>6 Q. Meaning the actual chemical</p> <p>7 reaction, like...</p> <p>8 A. Exactly, the chemical reaction</p> <p>9 for producing this in this instance.</p> <p>10 Q. And this exhibit indicates that</p> <p>11 he worked for AstraZeneca at the time?</p> <p>12 A. Correct, and he was a leading</p> <p>13 expert in genotoxic impurities at the time as</p> <p>14 well.</p> <p>15 Q. Okay. And then did you meet</p> <p>16 Dr. Russ Naven at that conference?</p> <p>17 A. I'm looking closely for the</p> <p>18 face, because I do not know that person.</p> <p>19 I do not think so.</p> <p>20 Q. How about Mike Urquhart, do you</p> <p>21 know that individual?</p> <p>22 A. I'm unsure at this conference</p> <p>23 whether I've met him. I've met him at a</p> <p>24 conference on impurities.</p>	<p>1 on the comparable case on EMS.</p> <p>2 Q. When you say the comparable</p> <p>3 case of EMS, what does EMS stand for?</p> <p>4 A. EMS stands for ethyl</p> <p>5 methanesulfonate.</p> <p>6 Q. And why did you refer to that</p> <p>7 as a comparable case?</p> <p>8 A. I refer to it as a comparable</p> <p>9 case because it's a ethylating agent that</p> <p>10 causes DNA adducts and DNA mutations in a</p> <p>11 very comparable way to these nitrosamines,</p> <p>12 and within their impurity issue in Viracept,</p> <p>13 they calculated a PDE that was accepted based</p> <p>14 on the understanding that low levels of this</p> <p>15 alkylating agent were repaired by DNA repair</p> <p>16 and the PDE calculation could be produced and</p> <p>17 accepted. So it's very comparable in my</p> <p>18 opinion.</p> <p>19 MS. BOGDAN: Just off the</p> <p>20 record for a second.</p> <p>21 (Discussion off the</p> <p>22 stenographic record.)</p> <p>23 BY MS. BOGDAN:</p> <p>24 Q. What is EMS?</p>

<p style="text-align: right;">Page 86</p> <p>1 A. I answered that in the previous 2 statement. EMS is ethyl methanesulfonate, an 3 alkylating agent. 4 Q. I should have asked the 5 question better. I'm -- is it a component -- 6 is it a drug itself? Is it a pharmaceutical? 7 A. It's a genotoxic impurity that 8 was found in a batch of Viracept, an 9 impurity. 10 Q. Okay. And Viracept would be 11 the pharmaceutical? 12 A. That was the affected 13 pharmaceutical to which a certain batch had 14 levels of EMS as an impurity. 15 Q. And EMS is not a nitrosamine, 16 correct? 17 A. It's definitely not a 18 nitrosamine, but it is an alkylating agent 19 with a very similar mutagenic and adduct 20 profile to these substances. 21 Q. Is it in the class of N-nitroso 22 compounds? 23 A. It is not. 24 Q. What is an N-nitroso compound?</p>	<p style="text-align: right;">Page 88</p> <p>1 chemicals that are encompassed in the larger 2 group of N-nitroso compounds? 3 A. Yes, that is correct, as far as 4 I'm aware. 5 Q. Can you describe the 6 characteristics of a nitrosamine? 7 MS. LOCKARD: Objection, form, 8 vague. 9 A. As stated, I'm not a chemist, 10 and I would not like to describe the chemical 11 nature of this group of nitroso compounds. 12 BY MS. BOGDAN: 13 Q. Do you generally know what 14 makes an N-nitroso -- or strike that. 15 Do you generally know what 16 makes a chemical an N-nitroso compound? 17 A. It would be the nitrogen group 18 and the oxygen group. 19 MS. LOCKARD: Did you say would 20 be the nitrogen group? 21 A. It would be descriptions around 22 the nitro -- nitrogen group and the oxygen 23 group. 24 BY MS. BOGDAN:</p>
<p style="text-align: right;">Page 87</p> <p>1 A. An N-nitroso compound covers 2 all of the compounds with nitro aspects to 3 them. 4 Q. And can you describe what you 5 mean by a nitro aspect to them? 6 A. I'm not a chemist, but there's 7 a group of these nitroso compounds to which 8 there are a hundred that contributes to TTC, 9 so chemically I would not like to expand on 10 what they are. 11 (Clarification requested by the 12 stenographer.) 13 A. TTC, threshold for 14 toxicological concern calculation. 15 BY MS. BOGDAN: 16 Q. And so because you're not a 17 chemist, you would defer to the chemists to 18 describe N-nitroso compounds as far as their 19 chemical composition and makeup? 20 A. I would defer to chemists for 21 that aspect. My focus would be on their 22 interaction with DNA, that repair, and the 23 link to carcinogenicity. 24 Q. Are nitrosamines a group of</p>	<p style="text-align: right;">Page 89</p> <p>1 Q. And aside from describing 2 N-nitroso compounds as having a nitrogen 3 group and an oxygen group, can you elaborate 4 any further with regard to the chemical 5 structure of N-nitroso compounds? 6 MS. LOCKARD: Objection, vague. 7 A. As stated, I would not describe 8 the chemical nature as I'm not a chemist. 9 BY MS. BOGDAN: 10 Q. Did you actually publish an 11 article with Dr. Müller? 12 A. I would have to look back over 13 my publication record to confirm or deny 14 that. I -- as I sit here today, I'm not 15 aware whether I have or have not. 16 Q. Did you produce any type of 17 writing, whether it be peer reviewed and 18 published or not, with regard to the EMS 19 matter that you worked with Dr. Müller on? 20 MS. LOCKARD: Objection, vague 21 as to "produce." 22 A. The EMS publications within my 23 publication record, the mechanistic studies 24 on EMS were linked to Hoffman-La Roche.</p>

<p style="text-align: right;">Page 90</p> <p>1 BY MS. BOGDAN:</p> <p>2 Q. When you say were linked to</p> <p>3 Hoffman-La Roche, meaning they were the</p> <p>4 authors?</p> <p>5 A. They were the industrial</p> <p>6 sponsors for the postdoctoral research that</p> <p>7 carried out the work and that grant paid for</p> <p>8 the researcher and for the consumables for</p> <p>9 that project to produce those related papers.</p> <p>10 Q. And did you work personally on</p> <p>11 those?</p> <p>12 A. I did not work personally on</p> <p>13 the wet work, the lab bench work, but I</p> <p>14 worked on the analysis of the data, the</p> <p>15 production of the study design and so on, and</p> <p>16 the drafting of the report within my</p> <p>17 publication list on this topic.</p> <p>18 Q. And was that work done at the</p> <p>19 university?</p> <p>20 A. At the university, correct.</p> <p>21 (Clarification requested by the</p> <p>22 stenographer.)</p> <p>23 A. Yes, that work was carried out</p> <p>24 at the university by my postdoc and myself.</p>	<p style="text-align: right;">Page 92</p> <p>1 A. I do not know her.</p> <p>2 Q. How about Dr. Qiu who works for</p> <p>3 Boehringer Ingelheim?</p> <p>4 MS. LOCKARD: Objection, vague.</p> <p>5 BY MS. BOGDAN:</p> <p>6 Q. Do you know Dr. Qiu?</p> <p>7 A. I do not.</p> <p>8 Q. Do you know Dr. Tom Van --</p> <p>9 it's -- I don't know how to pronounce the</p> <p>10 last name, W-I-J-K, who's with Abbott</p> <p>11 Healthcare?</p> <p>12 A. I do not know him and have not</p> <p>13 talked to him, but I have seen his work in</p> <p>14 presentations, so I know of him.</p> <p>15 Q. How about Dr. Catrin Hasselgren</p> <p>16 with Genentech, do you know her?</p> <p>17 A. As far as I'm aware, I do not</p> <p>18 know her either.</p> <p>19 Q. Okay. And with Intertek,</p> <p>20 Dr. Tino Otte, do you know him?</p> <p>21 A. As far as I'm aware, I do not</p> <p>22 know him.</p> <p>23 Q. Looking at this list of</p> <p>24 speakers, other than attending Dr. Teasdale's</p>
<p style="text-align: right;">Page 91</p> <p>1 BY MS. BOGDAN:</p> <p>2 Q. And what time period are we</p> <p>3 speaking of that the work was done?</p> <p>4 A. I would have to see my</p> <p>5 publication record for the exact dates. I</p> <p>6 think it's the Zair publication.</p> <p>7 Q. Is that in your CV,</p> <p>8 Dr. Johnson?</p> <p>9 A. I'm looking at my CV now. It's</p> <p>10 in my -- it's in my CV, Zair, et al.</p> <p>11 Z-A-I-R, et al., 2011, N-Methylpurine DNA</p> <p>12 Glycosylase Plays a Pivotal Role in the</p> <p>13 Threshold Response of Ethyl</p> <p>14 Methanesulfonate-Induced Chromosome Damage,</p> <p>15 in Toxicological Sciences.</p> <p>16 Q. Back to the exhibit that still</p> <p>17 should be up on your screen, there's a</p> <p>18 Dr. Wichard who works for Bayer.</p> <p>19 Do you see -- we're on the</p> <p>20 second column, second person down.</p> <p>21 A. I see him, and I'm looking at</p> <p>22 the others. I do not know that person.</p> <p>23 Q. How about Dr. Vanderkelen who</p> <p>24 worked for Nelson Labs? Do you know her?</p>	<p style="text-align: right;">Page 93</p> <p>1 presentation, does looking at this list of</p> <p>2 speakers refresh your recollection of any</p> <p>3 other presentations you attended?</p> <p>4 A. It reflects my recollection</p> <p>5 that I did not attend those other ones, and I</p> <p>6 focused on Andy Teasdale. I was aware he was</p> <p>7 an expert and went to his talk. I cannot</p> <p>8 recollect any others due to being chemistry</p> <p>9 focused and not in my area of interest or</p> <p>10 expertise.</p> <p>11 Q. What do you consider yourself</p> <p>12 an expert in?</p> <p>13 A. I consider myself an expert and</p> <p>14 I have been told by many people globally to</p> <p>15 be an expert in genetic toxicology. Of</p> <p>16 course I've been told I'm an expert in</p> <p>17 benchmark dose-response modeling. I've also</p> <p>18 been told by regulators that I have a high</p> <p>19 level of expertise in human health risk</p> <p>20 assessment as well.</p> <p>21 Q. The first area that you</p> <p>22 mentioned was genetic toxicology. Could you</p> <p>23 define genetic toxicology?</p> <p>24 A. Genetic toxicology is an area</p>

<p style="text-align: right;">Page 94</p> <p>1 of toxicology focused on compounds producing 2 genetic damage to DNA. To test for this, you 3 have a battery of mandated tests with OECD 4 guidelines, and for this particular topic, a 5 modification of that guideline within the ICH 6 guidance. 7 So it's a mandated series of 8 tests to test to see if genetic damage has 9 occurred from these compounds, the mechanism 10 of how it's occurred, and more advanced, of 11 what levels it does not occur, and so on. 12 So mandated part of industrial 13 and regulatory testing of compounds to see if 14 they're mutagenic or not, and potency and 15 mechanism and so on. 16 Q. Now, the second area that you 17 mentioned was benchmark dose-response 18 modeling. Would you please describe what 19 that is? 20 A. Benchmark dose statistical 21 modeling is applying a series of statistical 22 models to toxicology and cancer bioassay data 23 to derive a benchmark dose, and that 24 benchmark dose is defined as a point of</p>	<p style="text-align: right;">Page 96</p> <p>1 those data. 2 Q. Bringing it down to a little 3 bit more simple, what is actually a cancer 4 bioassay study, like what physically is it? 5 A. Physically, get a group of 6 rodents, treat them with a compound for the 7 lifetime of those rodents, sacrifice the 8 animals, carry out pathological assessment to 9 see levels of tumors and positions of tumors 10 all through the organs of those individuals. 11 Q. And when you say treat them 12 with a compound, is -- what is the purpose of 13 treating them with a compound? 14 A. It's different depending on 15 what the compound is and what it's predicted 16 to be, et cetera. If we want to see if a 17 substance is carcinogenic to animals, then we 18 carry out this test to see is something 19 carcinogenic in animals or not. 20 Then the more advanced version 21 of the assay, in an expanded one with 22 multiple doses, multiple numbers of animals, 23 you can carry out dose-response analysis and 24 actually define a level on that dose response</p>
<p style="text-align: right;">Page 95</p> <p>1 departure for those animal tests, and that's 2 wrapped up in itself. 3 And then the next area that 4 you'll ask me about will be risk assessment. 5 So that part is defining a point of departure 6 with advanced statistical modeling from 7 in vivo, relevant robust test systems. 8 That's what benchmark dose modeling is. 9 Q. What is cancer bioassay data? 10 A. In order to carry out a risk 11 assessment for cancer, the cancer bioassay 12 must be adhered to. There's guidelines on 13 this topic from the OECD, where it's 14 specified routes of administration, tissues 15 that should be assessed, study design, animal 16 husbandry and so on. 17 So there's a mandated way to 18 carry out cancer bioassay analysis in 19 rodents. This is in my list of references as 20 well. And from that, you get the best data 21 that adheres to this test guideline, and you 22 can do a hazard assessment on it if you're a 23 hazard-based organization. We can do a risk 24 assessment if we're talking about risks on</p>	<p style="text-align: right;">Page 97</p> <p>1 that you can extrapolate away from the animal 2 concentration to human. 3 And that's where we get to the 4 risk assessment, because we can use those 5 concentrations in that way. 6 Q. And is that the type of 7 methodology that was used in the Peto study 8 of NDMA and NDEA? 9 A. Yes. And that was one of the 10 most robust cancer bioassay studies that I've 11 actually ever seen. It's a really extensive 12 dataset that was fantastic for my benchmark 13 dose analysis and statistical modeling. 14 Q. And is it the most extensive 15 dataset that you have seen with regard to 16 NDMA and NDEA? 17 A. It is. For that endpoint of 18 cancer in animals, it definitely is. 19 Q. And the endpoint for that study 20 was actually cancer, correct? 21 MS. LOCKARD: Objection, form, 22 vague. 23 BY MS. BOGDAN: 24 Q. What was the endpoint of that</p>

<div>Page 102</div> <div>1 [REDACTED]</div> <div>21 [REDACTED]</div>	<div>Page 104</div> <div>1 [REDACTED]</div> <div>21 [REDACTED]</div>
<div>Page 103</div> <div>1 [REDACTED]</div> <div>14 [REDACTED]</div>	<div>Page 105</div> <div>1 [REDACTED]</div> <div>16 [REDACTED]</div>

Page 106

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12 BY MS. BOGDAN:
13 Q. You mentioned that you had
14 worked with doing risk assessments with
15 regulatory bodies, and I think you testified
16 that you had submitted risk assessments to
17 regulatory bodies.
18 Can you please tell me what
19 risk assessments you submitted to regulatory
20 bodies?
21 A. I've done numerous of these.
22 These are documented and carried out in a
23 consultancy role under Swansea Innovations in
24 my university, abiding to the roles of

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1 consultancy.
2 When we carried out the -- when
3 I carried out these risk assessments, I've
4 been doing numerous of these. One I did the
5 Cobalt Consortium on Cancer and carried out
6 the analysis, submitted it to the RIVM at
7 that time, and then to ECHA, the European
8 Chemicals Agency.
9 I carried on working on that
10 issue, and due to my working relationship
11 with RIVM, did some further work on Cobalt
12 with RIVM as well through -- with Wout Slob
13 as well.
14 The related ones to -- more
15 related to today's case, I've worked on
16 different industries, focused mostly on this
17 topic. If there's a genetic toxicant that I
18 can -- we understand the mechanism or we can
19 show that low levels are withstood, then we
20 carry out an in vivo dose-response analysis
21 to find the point of departure, and then
22 carry out the risk assessment.
23 So those are what I'm talking
24 about, and the ones related to today would be

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1 with the pharmaceutical companies, where I've
2 carried out those calculations on parent
3 drugs. So the whole drug, and then added a
4 safety factor to get to a level of human
5 intake that's okay for the clinical trials.
6 Calculated those, submitted them for a risk
7 assessment. Those have been accepted.
8 I've done similar ones for
9 genotoxic impurities within other
10 pharmaceutical products, carried out these
11 analyses, submitted them to the regulatory
12 bodies, and those have been accepted as well.
13 And that's my answer.
14 Q. You used the term "RIVM"? What
15 does that stand for?
16 A. I cannot say the exact term
17 because it's a Dutch -- there's some Dutch
18 words in there. RIVM, it's the Dutch
19 National Institute of Health, but those are
20 the correct letters.
21 Q. And that's the project you did
22 with the Cobalt Consortium on Cancer?
23 A. Yes.
24 Q. Who funded that research?

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1 A. It started with the Cobalt
2 Consortium, so the companies who produced
3 cobalt and had industrial exposure to cobalt.
4 Q. So they were the manufacturers
5 of cobalt that --
6 A. As far as I --
7 Q. -- that work?
8 (Clarification requested by the
9 stenographer.)
10 BY MS. BOGDAN:
11 Q. So it was the manufacturers of
12 cobalt that funded that work?
13 A. As far as I'm aware, and that
14 was through the Cobalt Consortium.
15 Q. And what was the purpose of
16 that study?
17 A. It was a hazard, not
18 risk-based, assessment. It was a
19 hazard-based assessment to see the potency of
20 cobalt as a carcinogen in these -- in the
21 cancer bioassay, so it was a hazard-based
22 potency assessment.
23 Q. And was the assessment with
24 regard to coming into contact with cobalt by

<p style="text-align: right;">Page 110</p> <p>1 breathing it, by ingesting it, by -- through 2 the skin or something else? 3 A. I cannot remember the route of 4 administration for the animal studies which I 5 assessed, but they were relevant at that 6 time. 7 Q. Do you know what exposure or 8 the type of exposure that the Cobalt 9 Consortium on Cancer was concerned about? 10 A. I do not know the -- I do not 11 know that at the current time. I did at the 12 time, but now I do not know that. 13 Q. Were they concerned about 14 cobalt coming from a medical device? 15 A. My understanding -- it may be 16 incorrect -- was battery production in 17 industry. The workers producing products 18 with cobalt, that was the concern. 19 Q. And this type of risk 20 assessment work that you did, was that 21 provided to the Cobalt Consortium on Cancer? 22 MS. LOCKARD: Objection, form, 23 misstates the testimony. 24 ///</p>	<p style="text-align: right;">Page 112</p> <p>1 with the regulators, did the RIVM hire you as 2 a consultant or did you interact with them as 3 a representative of the Cobalt Consortium on 4 Cancer? 5 A. The RIVM did not recruit me as 6 a consultant, so I would have been on behalf 7 of the Cobalt Consortium. 8 Q. Now, you also mentioned that 9 you had done risk assessments for 10 pharmaceuticals. Am I remembering that 11 correctly? 12 A. Yes, correct. 13 Q. Who hired you to do risk 14 assessments on behalf of -- or of 15 pharmaceuticals? 16 A. I could not recall all of the 17 companies, numerous companies, where I did 18 these assessments on their substances, 19 including GSK, Dart, and I would have to 20 recall to a list which resides with Swansea 21 Innovations to expand on that list. But none 22 of those were nitrosamines. 23 Q. And so you would do these risk 24 assessments at the request of the</p>
<p style="text-align: right;">Page 111</p> <p>1 BY MS. BOGDAN: 2 Q. You did a risk assessment for 3 the Cobalt Consortium on Cancer, correct? 4 A. It was a hazard-based 5 assessment, not a risk assessment. They're 6 slightly different. 7 Q. Right. Okay, I'm sorry, I 8 misspoke. I forgot you had made the 9 distinction. 10 So the hazard risk assessment 11 that you did for the Cobalt Consortium on 12 Cancer, was that submitted to any regulatory 13 authority? 14 MS. LOCKARD: Objection, form, 15 misstates the testimony. 16 A. As my understanding, created 17 the report. That was submitted to the 18 regulators, the RIVM in that regard. And I 19 worked with the RIVM. They were -- had an 20 active interest in my work. It was quite 21 advanced. And yes, they did submit to the 22 regulators. 23 BY MS. BOGDAN: 24 Q. And when you say you worked</p>	<p style="text-align: right;">Page 113</p> <p>1 pharmaceutical company and then provide the 2 risk assessment back to the pharmaceutical 3 company, correct? 4 A. Yes, that would be correct. I 5 would prepare the risk assessment in a 6 similar way to this, submit that to the 7 pharmaceutical company, correct. 8 Q. And it would be the 9 pharmaceutical company that would actually 10 present the risk assessment to the 11 regulators, correct? 12 MS. LOCKARD: Objection, form, 13 speculation. 14 A. The regulatory submissions 15 would include my documents in their 16 submission. 17 BY MS. BOGDAN: 18 Q. And you said they -- your work 19 did not involve nitrosamines, your previous 20 work? 21 A. What -- as far as I'm aware, 22 that is correct. That work did not include 23 nitrosamines. 24 Q. Did it involve contaminants in</p>

<p style="text-align: right;">Page 114</p> <p>1 pharmaceuticals?</p> <p>2 A. In some cases, they were</p> <p>3 impurity assessments, correct.</p> <p>4 Q. And how do you define an</p> <p>5 impurity?</p> <p>6 A. I would refer back to the</p> <p>7 impurity guidance within the ICH, including</p> <p>8 degradants, and there's a list within the ICH</p> <p>9 of what an impurity is defined as.</p> <p>10 Q. As you sit here today, how</p> <p>11 would you define an impurity?</p> <p>12 A. I would define impurity as a</p> <p>13 substance that's within a pharmaceutical -- a</p> <p>14 genotoxic impurity in pharmaceuticals as a</p> <p>15 substance that could be a degradant or a</p> <p>16 byproduct within the process of making the</p> <p>17 finished article.</p> <p>18 Q. Now, when you say a substance,</p> <p>19 that would be a chemical?</p> <p>20 A. That would be a chemical.</p> <p>21 That's how I would define "substance" in that</p> <p>22 statement.</p> <p>23 Q. And would it be a chemical that</p> <p>24 was not intended to be in the drug product?</p>	<p style="text-align: right;">Page 116</p> <p>1 demonstrated with, for example, the work of</p> <p>2 the Cobalt Consortium, I have that experience</p> <p>3 with cancer bioassay data as well. In some</p> <p>4 of my publications, you'll see -- such as</p> <p>5 when I work with the RIVM assessing cancer</p> <p>6 bioassay data and benchmark dose confidence</p> <p>7 intervals. I have upcoming projects on that</p> <p>8 with Health Canada as well. Then those would</p> <p>9 be covering cancers in addition to genetic</p> <p>10 toxicology.</p> <p>11 Q. So you look at chemicals that</p> <p>12 are carcinogens that are not necessarily</p> <p>13 genotoxic?</p> <p>14 A. My particular area of expertise</p> <p>15 is genotoxic carcinogens. I do not work with</p> <p>16 nongenotoxic carcinogens that act via</p> <p>17 different mechanisms to induce the cancer.</p> <p>18 My area of expertise would be</p> <p>19 mutagenic carcinogens where it's well</p> <p>20 characterized, and it could be through other</p> <p>21 genetic damage processes leading to the</p> <p>22 cancer.</p> <p>23 Q. What is your Ph.D. in? What</p> <p>24 field?</p>
<p style="text-align: right;">Page 115</p> <p>1 A. As an impurity, within this</p> <p>2 area of producing chemicals, there's an</p> <p>3 understanding that a hundred percent purity</p> <p>4 is not achievable, and this is why the ICH</p> <p>5 impurity regulation exists to instead talk</p> <p>6 about presence or absence, we talk about</p> <p>7 concentrations and levels of impurities that</p> <p>8 are acknowledged to be present in such</p> <p>9 substances and such drugs.</p> <p>10 Q. And would your risk assessments</p> <p>11 address the appropriate, in your opinion,</p> <p>12 levels that should be allowed in the drug</p> <p>13 products?</p> <p>14 A. They have done. They would be</p> <p>15 calculations to ensure that a human exposed</p> <p>16 to that level of that substance had no</p> <p>17 increased risk of whatever endpoint that was,</p> <p>18 so if it was mutation, mutation; if it was</p> <p>19 chromosome loss, then chromosome damage; if</p> <p>20 it's cancer, then cancer, in that regard.</p> <p>21 Q. And would your work be confined</p> <p>22 to the area of genotoxic risk assessment?</p> <p>23 A. It would not. That's my</p> <p>24 initial area of expertise, and as I</p>	<p style="text-align: right;">Page 117</p> <p>1 A. Ph.D., it was within the</p> <p>2 department of biology, now medicine. The</p> <p>3 title of the Ph.D. is Mechanistic</p> <p>4 Investigations of the Quantitative and</p> <p>5 Qualitative Effects of Genotoxicants. So I</p> <p>6 developed other understanding throughout that</p> <p>7 learning process, but my Ph.D. is in genetics</p> <p>8 and in genetic toxicology, and as you see</p> <p>9 from the title, in mechanisms underlying</p> <p>10 those, which include DNA repair, and also the</p> <p>11 quantitative aspects, including dose-response</p> <p>12 modeling, and qualitative, yes or no, effects</p> <p>13 of genotoxicants. So an expanded version of</p> <p>14 my Ph.D. title would include those different</p> <p>15 aspects.</p> <p>16 Q. But that is different than risk</p> <p>17 assessment, is it not?</p> <p>18 A. It is different to risk</p> <p>19 assessment. It's the initial step in risk</p> <p>20 assessment is defining points of departure</p> <p>21 that can then be used in risk assessment.</p> <p>22 So I initiated this expertise</p> <p>23 calculating those points of departure that</p> <p>24 could then be used for risk assessment. I</p>

<p style="text-align: right;">Page 118</p> <p>1 started my training on that data defining 2 those and then got to the stage of applying 3 that throughout my career. 4 Q. So risk assessment was not part 5 of your bachelor's degree and your Ph.D., 6 correct? 7 MS. LOCKARD: Objection, 8 compound. 9 BY MS. BOGDAN: 10 Q. Risk assessment training was 11 not part of your bachelor's degree studies, 12 correct? 13 A. Aspects of risk assessment 14 training were included in my Ph.D. My Ph.D. 15 was linked to the European Union PEPFAC 16 funding, which was to -- 17 Q. I -- 18 A. Pardon? 19 MS. LOCKARD: Can he finish? 20 BY MS. BOGDAN: 21 Q. I'm sorry, sir. I had asked 22 about your bachelor degree studies, not your 23 Ph.D. studies. 24 A. Oh, apologies. I heard you say</p>	<p style="text-align: right;">Page 120</p> <p>1 trained -- I was -- my training on risk 2 assessment was initiated. 3 Q. Did the work that you 4 personally did involve mechanisms and 5 dose response? 6 A. In this undergraduate project 7 on bisphenol A, mechanisms and dose response, 8 and then expanded application of that 9 information in the rest of the report. 10 Q. Did you actually perform the 11 risk assessment yourself or was that -- you 12 said linked to a risk assessment project. 13 Was the risk assessment project performed by 14 others? 15 A. That would be correct at that 16 time, and I was aware of those being -- those 17 taking place. 18 Q. And your Ph.D. is in genetic 19 toxicology through the department of biology? 20 A. I -- my Ph.D. was within 21 genetic toxicology, and within that, I 22 expanded on my undergraduate project again on 23 bisphenol A, and I think on -- on bisphenol A 24 and on alkylating agents and their mechanisms</p>
<p style="text-align: right;">Page 119</p> <p>1 both. 2 Q. So I'll read back my last 3 question. 4 Risk assessment training was 5 not part of your bachelor's degree studies, 6 correct? 7 A. In my bachelor's degree, I 8 carried out two modules on genetic toxicology 9 and information around hazard and risk 10 assessment in that module as taught by 11 Professor Jim Parry at that time. 12 I did an undergraduate project 13 on genetic toxicology, which was linked to 14 risk assessment through the analysis of 15 bisphenol A. You'll see my first publication 16 in 2002 was on bisphenol A, was on 17 mechanisms, was on dose response. That 18 linked to a European Union risk assessment 19 project on aneugens, and also the European 20 Food Safety Authority -- the U.K. version of 21 that, the Food Standards Agency, were also 22 involved and party to that big paper. 23 So I would say through those 24 modules and through my dissertation, I was</p>	<p style="text-align: right;">Page 121</p> <p>1 of action and their dose response. And I was 2 learning and understood the application of 3 that to hazard and risk assessment, and that 4 was at the Ph.D. stage. 5 Q. Did you actually do a hazard or 6 risk assessment as part of your Ph.D. thesis? 7 A. That was not included as part 8 of the output within my Ph.D. thesis, but I 9 attended numerous conferences where this was 10 discussed and included, and also my 11 supervisor was carrying these out and linked 12 to groups such as the committee on 13 mutagenicity where these were being carried 14 out. 15 So not entirely within this, 16 but through my training it was started at 17 that time, my understanding and training 18 around hazard and risk assessment. 19 Q. Do you consider yourself a 20 regulatory expert? 21 A. I've been considered by others, 22 including regulators, as a regulatory expert, 23 so to quote them, I would state that I'm 24 considered as an expert in regulatory</p>

<p style="text-align: right;">Page 122</p> <p>1 practice.</p> <p>2 With this particular focus on</p> <p>3 what we're talking about today, with</p> <p>4 dose response, when we're talking about PDE</p> <p>5 with acceptable intakes, with margins of</p> <p>6 exposure, yes, I am considered an expert in</p> <p>7 those particular applications within risk</p> <p>8 assessment.</p> <p>9 Q. And when you say you're</p> <p>10 considered an expert by others, who are those</p> <p>11 others?</p> <p>12 A. In verbal conversations -- and</p> <p>13 we can come back to names when we get that</p> <p>14 piece completed -- but the straightforward</p> <p>15 one would be I was on the expert panel for</p> <p>16 the European Medicines Agency on this topic,</p> <p>17 and I was a stated expert on that group.</p> <p>18 Q. And when did this take place</p> <p>19 and what group was this? Did you say the</p> <p>20 EMA?</p> <p>21 A. EMA, European Medicines Agency.</p> <p>22 I have a date somewhere.</p> <p>23 Q. Are you looking at your CV to</p> <p>24 try to --</p>	<p style="text-align: right;">Page 124</p> <p>1 A. The scientists that I remember</p> <p>2 and I know of -- I'm sure those -- that</p> <p>3 information is public for you to expand on my</p> <p>4 answer -- would be Bernd Kaina, Professor</p> <p>5 Bernd Kaina of Mainz University, who is the</p> <p>6 global expert on MGMT and DNA repair.</p> <p>7 There were other experts, I</p> <p>8 can't remember their names. There was an</p> <p>9 epidemiology expert. There was an expert</p> <p>10 that had been involved in the cigarette smoke</p> <p>11 instance, and there was -- I think there was</p> <p>12 ten in total, and apologies for not</p> <p>13 remembering the names.</p> <p>14 Oh, apologies, one more. Jan</p> <p>15 van Benthem from the RIVM. Jan van Benthem.</p> <p>16 Q. And when you said you</p> <p>17 considered yourself a regulatory expert, is</p> <p>18 that limited to points of departure,</p> <p>19 benchmark dose, dose response within the</p> <p>20 field of genetic toxicology?</p> <p>21 A. I'd expand that statement to</p> <p>22 include based on cancer bioassay data as</p> <p>23 well.</p> <p>24 Q. Do you consider yourself an</p>
<p style="text-align: right;">Page 123</p> <p>1 A. I am looking at my CV to try to</p> <p>2 find a date. Okay.</p> <p>3 On my CV at the bottom of the</p> <p>4 Awards, Achievements, Positions of</p> <p>5 Responsibility, invited expert to EMA 2020</p> <p>6 nitrosamine expert consultation, with the</p> <p>7 number afterwards, for the record,</p> <p>8 EMA/80573/2020.</p> <p>9 But to be invited to an expert</p> <p>10 group by a regulatory body assumes that they</p> <p>11 consider you as an expert.</p> <p>12 Q. And where are you referring to</p> <p>13 on your CV, Doctor, just so that I make sure</p> <p>14 I'm in the same place.</p> <p>15 A. Hopefully it's the first page.</p> <p>16 Mine says page 1, and I think it is page 1.</p> <p>17 There's my name, there's my address --</p> <p>18 Q. Oh, at the bottom of the --</p> <p>19 A. Awards, Achievements -- Awards,</p> <p>20 Achievements and Positions of Responsibility.</p> <p>21 It's the bottom bullet point in that section.</p> <p>22 Q. Okay. Who else was invited as</p> <p>23 an expert to that EMA 2020 nitrosamine</p> <p>24 consultation?</p>	<p style="text-align: right;">Page 125</p> <p>1 expert in epidemiology?</p> <p>2 A. I do not consider myself an</p> <p>3 expert in epidemiology.</p> <p>4 Q. Directing you to the Amended</p> <p>5 List of Materials Considered -- now, have we</p> <p>6 marked that as an exhibit or is that part of</p> <p>7 the -- your report that's already been</p> <p>8 marked?</p> <p>9 A. Can you clarify the question?</p> <p>10 Q. I'm not sitting there with you</p> <p>11 in the room, so I can't see if the report --</p> <p>12 your report that's been marked already as an</p> <p>13 exhibit has Exhibit A attached to it and</p> <p>14 Exhibit B, or if it's standing alone, so to</p> <p>15 speak.</p> <p>16 (Conference out of the hearing</p> <p>17 of the stenographer.)</p> <p>18 MS. LOCKARD: They were served</p> <p>19 together. It was served as an exhibit</p> <p>20 with the report, but Exhibit 2 is just</p> <p>21 the report.</p> <p>22 MS. BOGDAN: Okay.</p> <p>23 MS. LOCKARD: So he's got the</p> <p>24 amended list in his hand if we want to</p>

<p style="text-align: right;">Page 126</p> <p>1 mark it as Exhibit 6.</p> <p>2 MS. BOGDAN: So could we pull</p> <p>3 up, then, the amended Exhibit A and B</p> <p>4 of his report, and then mark that</p> <p>5 separately, if it was not included</p> <p>6 with the report itself?</p> <p>7 THE STENOGRAPHER: Just to</p> <p>8 clarify, A and B together will be</p> <p>9 Exhibit 6?</p> <p>10 TRIAL TECHNICIAN: Exhibit A</p> <p>11 and B are part of the report.</p> <p>12 Exhibit A starts on page 70, Exhibit B</p> <p>13 starts on page 79.</p> <p>14 MS. BOGDAN: That's perfect. I</p> <p>15 just --</p> <p>16 TRIAL TECHNICIAN: Which page</p> <p>17 would you like to see, Exhibit A,</p> <p>18 which is his CV?</p> <p>19 MS. BOGDAN: No, I would like</p> <p>20 to go to, I guess what you said was</p> <p>21 page 79, which would be the start of</p> <p>22 the Amended List of Materials</p> <p>23 Considered.</p> <p>24 TRIAL TECHNICIAN: Okay.</p>	<p style="text-align: right;">Page 128</p> <p>1 there's hundreds?</p> <p>2 A. I prefer not to make guesses,</p> <p>3 but it looks like a large number, towards</p> <p>4 that amount.</p> <p>5 Q. Now, are these materials that</p> <p>6 are listed here materials that you were</p> <p>7 provided by counsel?</p> <p>8 A. So on page 1 would be the</p> <p>9 materials passed on by GT. If that's another</p> <p>10 name for counsel, then that would be that.</p> <p>11 Q. So the MDL -- let me just -- so</p> <p>12 the record is clear, I'm sorry, I didn't mean</p> <p>13 to speak over you. There's just a little</p> <p>14 delay.</p> <p>15 The -- so under Materials</p> <p>16 Considered, the MDL pleadings and general</p> <p>17 documents were materials you got from</p> <p>18 counsel, correct?</p> <p>19 A. Correct.</p> <p>20 Q. The expert reports --</p> <p>21 A. Yeah, again, from --</p> <p>22 Q. -- would be materials you got</p> <p>23 from counsel?</p> <p>24 A. I would agree with that. Thank</p>
<p style="text-align: right;">Page 127</p> <p>1 MS. LOCKARD: I -- the version</p> <p>2 we have here doesn't have page numbers</p> <p>3 on it for the record, but he does have</p> <p>4 the amended list in front of him.</p> <p>5 MS. BOGDAN: I think it's just</p> <p>6 the page number of the PDF. It</p> <p>7 doesn't have a -- and we can refer to</p> <p>8 it at this point with the page number</p> <p>9 that's right on the bottom of the List</p> <p>10 of the Materials Considered.</p> <p>11 BY MS. BOGDAN:</p> <p>12 Q. So do you recognize this</p> <p>13 document, sir?</p> <p>14 A. I recognize the document that's</p> <p>15 being presented on Zoom, correct.</p> <p>16 Q. Now, this document is 25 pages</p> <p>17 long, I believe?</p> <p>18 A. I believe that too.</p> <p>19 Q. And how many documents are</p> <p>20 listed on the Amended List of Materials</p> <p>21 Considered? Do you know?</p> <p>22 A. I have not counted them in this</p> <p>23 format, no.</p> <p>24 Q. Would you agree with me that</p>	<p style="text-align: right;">Page 129</p> <p>1 you for highlighting them.</p> <p>2 Q. The next section, which is</p> <p>3 entitled Deposition Transcripts With</p> <p>4 Exhibits, are those materials that you</p> <p>5 received from counsel?</p> <p>6 A. Yes. As far as I'm aware, yes,</p> <p>7 definitely.</p> <p>8 Q. And they continue on to page 2</p> <p>9 as well. Again, materials from counsel?</p> <p>10 A. These were provided by counsel.</p> <p>11 Q. Okay. Now we get to a section</p> <p>12 called Regulatory Guidances and Documents.</p> <p>13 Do you see that?</p> <p>14 A. I do see that.</p> <p>15 Q. Were these provided by counsel?</p> <p>16 A. Many of these were -- these --</p> <p>17 so a lot of this is from my own research and</p> <p>18 from preparing for presentations and</p> <p>19 preparing my report. I would have got a lot</p> <p>20 of these independently.</p> <p>21 I think where we see in the</p> <p>22 second column like a Teva mark on it, you may</p> <p>23 interpret this as being passed on by counsel,</p> <p>24 but the ICH M7 guidance is obviously</p>

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1 something that I would have looked at and
2 that I have to reference as well.
3 So these documents are ones
4 that I researched and digested, considered
5 and went into my report, independently of
6 counsel, as far as I'm aware.
7 Q. Okay. If we could go to
8 page 3, please. And there's a document that
9 is about two-thirds of the way down the page,
10 it starts with 2019 ICH Q3D(R1).
11 Do you see that?
12 A. I do see that.
13 Q. That was added in the Amended
14 List of Materials Considered. Why was that
15 added?
16 A. To ensure that there was a
17 latest revision of the ICH Q3D guidance which
18 relates to this, because there's an expanded
19 version of the PDE calculation within that.
20 Q. And that was not previously
21 listed on your materials considered, correct?
22 A. Correct. That was a typo.
23 Q. Even though the date of your
24 report was August of 2020, correct?

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1 A. The date of my report was
2 August 2020.
3 Q. So at the time that your report
4 was issued, that 2019 guidance was in
5 existence, correct?
6 A. Yeah, that's correct.
7 Q. Now let's go to the next
8 section on page 5, which is Literature and
9 Standards.
10 A. I can see on your screen and I
11 have this in front of me.
12 Q. Okay. Where did those
13 materials considered originate from? Were
14 they provided by counsel or through your
15 research?
16 A. These would be through my
17 research and included in developing my
18 understanding of this topic from contribution
19 to this work and to just developing my
20 understanding of the topic, so from myself.
21 Q. If we could go to the next
22 page, please. I see a lot of references in
23 this materials considered list to TEVA-MDL.
24 Do you see that over on the

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1 right-hand column?
2 A. I see that, yes.
3 Q. Who were you originally hired
4 by as an expert in this case?
5 A. By GT.
6 Q. On behalf of what defendant?
7 A. On behalf of Teva, as far as
8 I'm aware.
9 Q. Are you serving as an expert on
10 behalf of defendants other than Teva?
11 A. Yes, I am.
12 Q. When did that change?
13 A. That changed at the beginning
14 of this year, when my role changed from a
15 consultant, where I was developing an
16 understanding of this topic, to the
17 preparation of my report. At that time I was
18 made aware by counsel that I was working for
19 a wider group of affected companies.
20 Q. Did they tell you who those
21 companies were?
22 A. They did, yes.
23 Q. And who are those companies?
24 A. Well, my pronunciation and

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1 recollection may not be precise, include
2 Mylan, ZHP, Princeton and one beginning with A
3 with "bindo" at the end, I think. There may
4 be more. That's my recollection. So more
5 than Teva.
6 Q. Aurobindo?
7 A. Yeah, that sounds correct.
8 Q. How about Hetero?
9 A. Hetero, yes, I think I'm
10 representing them as well. Yes, they're
11 included.
12 Q. As we go on in this materials
13 considered list, especially once we get to
14 page 19, which has Company Documents
15 Produced --
16 A. I'm going to look at your
17 screen for this bit.
18 Q. -- all of those documents
19 appear to be Teva documents; is that correct?
20 Teva/Mylan?
21 A. That's what it states here.
22 Q. Did you read all these
23 documents?
24 A. I had access to and considered

<p style="text-align: right;">Page 134</p> <p>1 these documents.</p> <p>2 Q. And when you say I had access</p> <p>3 to and considered them, what does that mean</p> <p>4 as far as your activity with regard to these</p> <p>5 documents?</p> <p>6 A. If the document was relevant to</p> <p>7 my risk assessment, then I read it. If not,</p> <p>8 I would be aware of it and had access to it.</p> <p>9 Q. So that means you opened each</p> <p>10 and every one of these documents that are</p> <p>11 listed under Company Documents Produced to</p> <p>12 make that determination?</p> <p>13 A. If the title was in the name</p> <p>14 and it didn't look relevant, then maybe not.</p> <p>15 But yes, I would have opened all the ones</p> <p>16 that were relevant and considered whether to</p> <p>17 bring in information from other ones as well.</p> <p>18 Q. And if we go on to page 20, all</p> <p>19 the documents on that page are also Teva</p> <p>20 documents, correct, as far as how they're</p> <p>21 identified?</p> <p>22 A. As far as how they're</p> <p>23 identified, they are Teva documents on this</p> <p>24 page.</p>	<p style="text-align: right;">Page 136</p> <p>1 documents, correct?</p> <p>2 A. I can see that that's correct</p> <p>3 from what you've just said on this document.</p> <p>4 Q. And then moving on to page 24,</p> <p>5 again, we have some Aurobindo documents, some</p> <p>6 Mylan documents and some Teva documents, with</p> <p>7 one document towards the very, very bottom,</p> <p>8 second up from the bottom, that says ZHP</p> <p>9 Response to DMF Information Request Letter,</p> <p>10 Princeton.</p> <p>11 Do you see that?</p> <p>12 A. I do see that.</p> <p>13 Q. Did you ask for more company</p> <p>14 documents to be produced from ZHP at the time</p> <p>15 that you were asked to serve as an expert for</p> <p>16 all defendants?</p> <p>17 A. I cannot recall requesting that</p> <p>18 information.</p> <p>19 Q. Is this materials considered</p> <p>20 list comprehensive of all of the materials</p> <p>21 that you considered in forming your opinions</p> <p>22 in this matter?</p> <p>23 A. It is. From my understanding,</p> <p>24 this is very comprehensive.</p>
<p style="text-align: right;">Page 135</p> <p>1 Q. And moving to page 21, they're</p> <p>2 all identified as Teva documents, correct?</p> <p>3 A. According to this page, they</p> <p>4 are identified on the right column as Teva</p> <p>5 documents, and then you can see from some of</p> <p>6 the statements, HHA for valsartan produced --</p> <p>7 products provided by Mylan, et cetera. So</p> <p>8 the other companies do appear here as well.</p> <p>9 Q. Do you have any understanding</p> <p>10 of any relationship between Teva and Mylan?</p> <p>11 A. I am aware that some of the</p> <p>12 companies made the API and then the generic</p> <p>13 companies included those APIs in the</p> <p>14 products; and the exact relationship, I will</p> <p>15 not comment on now.</p> <p>16 Q. If we look at page 22, they're</p> <p>17 also all Teva documents, identified as such?</p> <p>18 A. Yeah, according to the right</p> <p>19 column there, they're stated as Teva</p> <p>20 documents.</p> <p>21 Q. And then on page 23, we have</p> <p>22 some Teva documents, and then there are a few</p> <p>23 documents with Auro or APL, which the</p> <p>24 description indicates are Aurobindo</p>	<p style="text-align: right;">Page 137</p> <p>1 Q. So if a document is not on this</p> <p>2 list, you did not consider it?</p> <p>3 A. I've been working on this topic</p> <p>4 for my whole career and read many documents</p> <p>5 that formed my expertise in this area, and</p> <p>6 those would lead to my ability to make these</p> <p>7 risk assessment judgments.</p> <p>8 So in that regard, this is</p> <p>9 comprehensive of my decision, and I would</p> <p>10 support that these were comprehensive and</p> <p>11 linked to my report entirely, but I wanted to</p> <p>12 make that statement as well, that I've always</p> <p>13 worked on this topic and I've read many</p> <p>14 documents in this area as well.</p> <p>15 Q. With regard to internal company</p> <p>16 documents that would have been produced by</p> <p>17 the defendants in the litigation, if the</p> <p>18 document is not on this list of materials</p> <p>19 considered, is it fair to assume that you did</p> <p>20 not consider it?</p> <p>21 A. From my understanding, that</p> <p>22 would be correct.</p> <p>23 Q. Do you know of the journal</p> <p>24 Environmental and Molecular Mutagenesis?</p>

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1 A. I do know of that journal, yes.
2 Q. And how do you know of that
3 journal?
4 A. I know of that journal, it's a
5 very good journal in this area of genetic
6 toxicology. It's linked to the American
7 Environmental and Genomic Society. It's very
8 highly linked at the current time to
9 Health Canada, which have been senior editors
10 on it previous to -- they still contain many
11 Health Canada experts, and within my area of
12 genetic toxicology, it's a preferred journal
13 for many experts, including the regulatory
14 experts, where we see it as a top journal in
15 genetic toxicology.
16 Q. Who is the editor-in-chief of
17 Environmental and Molecular Mutagenesis?
18 A. I think it's -- at the current
19 time it's Bhaskar Gollapudi. And I think
20 previous to that was -- apologies. Bhaskar
21 Gollapudi at the current time, and for our
22 paper which we published this year, the
23 editor was Carol York -- Carol Yauk, Y-A-U-K,
24 who handled the publication because Bhaskar

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1 was a coauthor on the publication. So she
2 was editor for this latest EMM publication on
3 PDE. Apologies for the long answer.
4 Q. So Bhaskar Gollapudi is the
5 editor-in-chief of Environmental and
6 Molecular Mutagenesis even currently,
7 correct?
8 A. I think that is correct, but
9 the leadership changes frequently, so I think
10 it's correct to the best of my knowledge.
11 Q. But for the purposes of the
12 publication entitled Permitted Daily Exposure
13 Limits For Noteworthy N-nitrosamines,
14 Carol -- did you say Yauk?
15 A. I think that's a suitable way
16 of pronouncing it.
17 Q. -- served that role of editor
18 because he was a named author in the article,
19 correct?
20 A. Correct, yes. And I think
21 that's standard practice in publishing as
22 well.
23 Q. When were you first retained as
24 a consultant to do work on this matter?

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1 A. I think we opened discussions
2 with GT and Teva at the beginning of 2019,
3 and that relates to my first invoice in 2019.
4 Q. Do you have a copy of that
5 first invoice that you had in 2019 with you?
6 A. It is currently not in front of
7 me.
8 MS. BOGDAN: Does counsel have
9 a copy of that? The first invoice
10 that we have in the production is in
11 2020.
12 MS. LOCKARD: I have hard
13 copies. Are you using one as an
14 exhibit?
15 MS. BOGDAN: I would like to
16 use all of the invoices as exhibits,
17 and I don't believe the 2019 invoice
18 was in the production.
19 THE WITNESS: I'm --
20 MS. LOCKARD: Hold on, there's
21 no question.
22 The invoices were all in the
23 production.
24 MS. BOGDAN: We have pulled

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1 them out, and the first one starts in
2 2020.
3 MS. LOCKARD: Yeah, he -- he
4 may have misspoke. You can ask him
5 about it, but we have all the
6 invoices.
7 BY MS. BOGDAN:
8 Q. Dr. Johnson, did you do work in
9 2019 on this project for Teva?
10 A. I became -- we signed the
11 documents in 2019, and I misspoke. It was
12 2020 for the invoice, I think. But you see
13 from my recollection of the dates, we need to
14 go by the invoice.
15 Q. Did you do work for a period of
16 time before you billed?
17 A. I have it in front of me. The
18 date I misspoke on. I said 2019. The date
19 is actually the 11th of the 9th, 2020, the
20 sum of 30,000 --
21 MS. LOCKARD: No. Just listen
22 to the question. Just hold on.
23 You're racing through.
24 THE WITNESS: Apologies.

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1 MS. BOGDAN: Why don't we pull
 2 up the exhibit that's entitled
 3 Invoices, and we can mark these.
 4 (Whereupon, Deposition Exhibit
 5 Johnson-6, Invoices, JOHNSON000037 -
 6 JOHNSON000044, was marked for
 7 identification.)
 8 THE STENOGRAPHER: That's
 9 Exhibit 6.
 10 MS. LOCKARD: Okay. And is
 11 this a collection of all four?
 12 MS. BOGDAN: I believe so, that
 13 they were put into one exhibit.
 14 Is that an eight-page exhibit,
 15 because there's fronts and backs, of
 16 all four invoices? I could ask our
 17 tech.
 18 TRIAL TECHNICIAN: Eight pages
 19 total in this file.
 20 MS. BOGDAN: Right, okay. So
 21 there's fronts and backs of each,
 22 so...
 23 TRIAL TECHNICIAN: Looks like a
 24 total of four invoices, yes.

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1 MS. BOGDAN: Okay. So yes,
 2 they're all together. So this is
 3 Exhibit 6.
 4 BY MS. BOGDAN:
 5 Q. Doctor, I'd ask you if you can
 6 please take a look at the first page of
 7 Exhibit 6, and tell me if you recognize that
 8 document.
 9 A. I do recognize that document.
 10 Q. And what do you recognize that
 11 document to be?
 12 A. I recognize this document to be
 13 my first invoice to GT on this topic.
 14 Q. Did you have any invoices that
 15 you submitted to Teva for your work on this
 16 project?
 17 A. No, not that I'm aware of, no.
 18 Q. Okay. And does this first
 19 invoice encompass all your work up until the
 20 date of the invoice?
 21 A. That is -- that would be
 22 correct.
 23 Q. And that would be 91 hours of
 24 time?

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1 A. That's -- that sounds correct,
 2 at my rate. Yes, that sounds correct.
 3 Q. When did you begin your work?
 4 That 91 hours of work, when did it start?
 5 A. I cannot give an exact date
 6 because I do not know that answer.
 7 Q. Can you give an approximate
 8 number of months you've been working on this
 9 project before submitting your invoice in
 10 November of 2020?
 11 MS. LOCKARD: Objection, form.
 12 A. I could not --
 13 MS. LOCKARD: Vague.
 14 A. I would not want to approximate
 15 that, but I can confirm I did count -- I did
 16 carry out this amount of hours.
 17 BY MS. BOGDAN:
 18 Q. Did you keep a record of the
 19 number of hours you worked by day to then
 20 come up with the 91-hour total that's
 21 reflected in the invoice that's been marked
 22 as Exhibit 6?
 23 A. At the time I would have done,
 24 and I don't need that document anymore, and

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1 don't have that, that time. I've got that
 2 for the current time and the time I have yet
 3 to invoice for.
 4 Q. Did you do work on this project
 5 in the year 2019?
 6 MS. LOCKARD: Objection, form,
 7 vague as to "project."
 8 A. I do not know the answer to
 9 that.
 10 BY MS. BOGDAN:
 11 Q. Who first contacted you about
 12 serving as a consultant for Teva?
 13 A. Raphael Nudelman, and we linked
 14 with GT.
 15 Q. Do you have any record as to
 16 when Raphael Nudelman contacted you?
 17 A. I do not have that record
 18 personally.
 19 Q. How did he contact you?
 20 A. I would predict by e-mail.
 21 Q. Did you save that e-mail?
 22 A. I do not know.
 23 Q. What did Ralph say in that
 24 e-mail?

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1 A. I do not know. The assumption
 2 would be to initiate consultancy with GT.
 3 MS. LOCKARD: Don't speculate,
 4 please. If you remember, you can
 5 answer, but you don't have to assume
 6 or speculate.
 7 THE WITNESS: Okay.
 8 BY MS. BOGDAN:
 9 Q. Generally, what did Ralph
 10 communicate to you in that e-mail? Not the
 11 exact words he used, but generally, what was
 12 the e-mail about?
 13 A. I think it was to explain my
 14 work to Teva.
 15 Q. And when you say explain my
 16 work, what do you mean by that?
 17 A. My presentations on this topic
 18 at that time, explain that work to Teva,
 19 yeah.
 20 Q. Meaning explain the type of
 21 work you do?
 22 A. Explain the slide set
 23 presentation that I had delivered to
 24 Impurities conferences to Teva.

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1 Q. Is that like the Impurities
 2 conference that took place in June of 2018?
 3 A. Exactly that.
 4 Q. Did you present that
 5 information at more seminars than the June of
 6 2018 one that took place in Germany?
 7 A. I did present the evolving
 8 level of work at other Impurities
 9 conferences.
 10 Q. And when did those take place?
 11 A. I do not know exact dates.
 12 Frequently over the last couple of years.
 13 Q. Do you know where they took
 14 place?
 15 A. Before the travel ban, in
 16 Berlin; Mainz, Germany. And then travel
 17 ban -- post travel ban, via online
 18 conferences.
 19 Q. So there are two in-person that
 20 you remember?
 21 A. In Berlin and Mainz, Germany
 22 that I remember.
 23 Q. And how many online conferences
 24 have you done?

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1 A. I have done -- I do not know
 2 the number and will not approximate.
 3 Q. Has there been more than one?
 4 A. There has been more than one.
 5 Q. Has there been more than 10?
 6 A. I do not know.
 7 Q. And these invoices are in
 8 pounds?
 9 A. These invoices are in Great
 10 British pounds.
 11 Q. And who generates these
 12 invoices?
 13 A. Swansea Innovations generates
 14 these invoices.
 15 Q. Is Swansea Innovations separate
 16 from Swansea University?
 17 A. There's a good statement in
 18 here to answer this question. Swansea
 19 Innovations is a wholly owned subsidiary of
 20 Swansea University.
 21 Q. And you're referring to right
 22 on the invoice itself where you're reading
 23 that?
 24 A. Correct. On your screen too.

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1 Q. Are you an employee of Swansea
 2 Innovations?
 3 A. I'm an employee of Swansea
 4 University and carry out consultancy through
 5 Swansea Innovations.
 6 Q. And when employees of Swansea
 7 University do consultant-type work, is that
 8 done through this wholly owned subsidiary?
 9 A. Yes, it is.
 10 Q. And as such, Swansea
 11 Innovations bills for your time?
 12 A. That would be correct.
 13 Q. And then how are you
 14 compensated for your work doing consultant
 15 services like you've done in this case for
 16 Teva?
 17 A. Swansea Innovations takes 20%
 18 of this value. My college, Swansea
 19 University Medical School, takes 5% of this
 20 value. The remaining funds go into that
 21 month's paycheck through PAYE to account for
 22 tax, et cetera.
 23 Q. And what does Swansea
 24 Innovations use with the percentage that it

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1 retains?
2 A. I do not know. I should not
3 assume.
4 Q. Does all your consultant-type
5 work go through Swansea Innovations?
6 A. Yes.
7 Q. What percentage of your income
8 per year is derived from doing consultant
9 work?
10 A. I have not made that
11 calculation.
12 Q. Can you provide an estimate?
13 A. My wage is 60,000.
14 (Clarification requested by the
15 stenographer.)
16 MS. LOCKARD: Yeah, I just want
17 to object if we're asking him about
18 his salary, but I --
19 MS. BOGDAN: Yeah, I didn't ask
20 him about his salary. I was asking
21 about the percentage of his income
22 that he derives from doing consulting
23 work.
24 MS. LOCKARD: Yeah, if you can

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1 do the math in your head --
2 THE WITNESS: Apologies.
3 MS. LOCKARD: It's fine. But a
4 percentage, not amounts.
5 A. It is -- I have my wage, which
6 is a value. My consultancy is half of that
7 value on top of that value.
8 BY MS. BOGDAN:
9 Q. So an additional 50%?
10 A. That's a better statement --
11 (audio malfunction) --
12 (Clarification requested by the
13 stenographer.)
14 A. That's a better statement.
15 That's an additional 50%, is the average for
16 my consultancy work.
17 BY MS. BOGDAN:
18 Q. If we could go to the next
19 invoice that's dated April 20th, 2021, and
20 that's for an additional 35 hours of work?
21 A. Okay. Yeah, I agree, 35 hours
22 of work additional. Yes, agree.
23 Q. Okay. And then the next -- I
24 think we have the wrong exhibit up. Okay.

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1 Then the next invoice in that
2 same exhibit, which is dated -- is it dated
3 July 5th, 2021 or May 7th, 2021?
4 A. This is the English format, and
5 it's July 5th.
6 Q. Thought so. Okay.
7 And that's for an additional
8 35 hours of work?
9 A. Yeah, I agree with this, yes.
10 Q. Okay. And then the last
11 invoice is July 28, 2021, and that's for an
12 additional 70 hours of work, correct?
13 A. Yeah, I agree that's correct.
14 Q. Did you keep any type of record
15 of what actual work you did, meaning
16 something that's itemized as to what you
17 spent your hours doing?
18 A. No, I did not.
19 Q. So other than these invoices,
20 there's no written record of how you spent
21 that time?
22 A. Correct, no written record of
23 how I spent the time.
24 Q. Do these invoices include all

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1 the time that you spent up until the time
2 that you generated your written report?
3 A. Yes, they include that time
4 within these invoices.
5 Q. If we could please pull up an
6 e-mail, which is Teva document 443142.
7 (Whereupon, Deposition Exhibit
8 Johnson-7, E-mail(s) re: Limit of NDEA
9 in Sartans, TEVA-MDL2875-00443142, was
10 marked for identification.)
11 THE STENOGRAPHER: This will be
12 Exhibit 7.
13 MS. BOGDAN: Mark it Exhibit 7.
14 BY MS. BOGDAN:
15 Q. Doctor, Exhibit 7 should now be
16 hopefully up on your screen. Can you see
17 that?
18 A. I can see it in very small
19 text. Is this available in the other format?
20 Excellent.
21 MS. LOCKARD: I'm sorry for the
22 interruption, but I can't get anything
23 past Exhibit 5 on my document box. Is
24 it just me?

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1 (Technical comments off the
2 stenographic record.)
3 MS. BOGDAN: Did that work?
4 MS. LOCKARD: I have it now.
5 Do you have it, Dr. Johnson?
6 THE WITNESS: I have that now,
7 thank you.
8 BY MS. BOGDAN:
9 Q. This is an e-mail from Ralph
10 Nudelman dated November 14th, 2018, to an
11 individual by the name of Claire Lyons.
12 Do you know Claire Lyons?
13 A. It does not ring a bell. I do
14 not think I know Claire Lyons.
15 Q. And Corey Sawyer is copied on
16 it. Do you know Corey Sawyer?
17 A. As far as I understand, I do
18 not know Corey Sawyer.
19 Q. And in this e-mail, if I could
20 direct your attention to the first paragraph,
21 which reads: Claire, from so many e-mails on
22 this topic, I lost track of what we had
23 previously discussed, and I would like to go
24 back to an e-mail I wrote on September 20th,

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1 copy attached, where I calculated a limit for
2 NDEA based on BMDL10 and not on linear
3 extrapolation from the TD50.
4 Then, open parens: There were
5 several follow-up e-mails to that one with
6 further clarifications, close parentheses,
7 period.
8 Do you see that sentence?
9 A. I do see that sentence.
10 Q. Did you provide to Ralph
11 Nudelman a calculation limit for NDEA based
12 upon BMDL10 --
13 A. Not that -- I'll let you --
14 Q. -- prior to November 14th,
15 2018?
16 A. This was linked to my
17 presentation at the former meeting where I
18 presented a BMDL10 analysis on these
19 compounds, and this will relate to that
20 presentation and slide set. Nothing more.
21 Q. Did Raphael Nudelman attend
22 your presentation?
23 A. Yes, I think that he did.
24 Q. And as part of your

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1 presentation, you presented on that exact
2 issue?
3 A. I'm confident that I did.
4 Q. And you presented on a
5 benchmark dose limit as opposed to linear
6 extrapolation from a TD50?
7 A. I'm confident that I did, yes.
8 Q. And did you provide any type of
9 written materials to the attendees of that
10 seminar?
11 A. Not that I recall.
12 Q. Was it presented by way of a
13 PowerPoint?
14 A. It was presented by way of a
15 PowerPoint.
16 Q. Were the attendees given copies
17 of the PowerPoints that were used by the
18 presenters?
19 A. I do not know.
20 Q. As a speaker, did you have to
21 provide a copy of your PowerPoint to the
22 seminar organizers?
23 A. I do not know. Conferences act
24 in that regard in different ways.

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1 Q. Do you still have that
2 particular slide where you presented a BMDL10
3 limit for NDEA?
4 A. I have multiple slides with
5 that statement in addition to my publication
6 on that topic.
7 Q. And has the calculation
8 basically been the same since 2018 for the
9 BMDL10 for NDEA?
10 A. The full publication, I would
11 reanalyze the data to ensure the precision,
12 so because there's prepublished data, there
13 is room for that number to change.
14 Q. Do you know what that number
15 was in 2018 when you presented at the seminar
16 that Raphael Nudelman went to?
17 A. No, I do not.
18 Q. Would you be able to search
19 your records to see if you still had a copy
20 of that PowerPoint that was presented in
21 2018?
22 A. My way of working is I get the
23 slide date and update it for the next
24 conference, so I wouldn't be confident in

<p>Page 158</p> <p>1 finding that.</p> <p>2 Q. You mentioned earlier in your</p> <p>3 testimony the name of the company that</p> <p>4 organized this conference. What was the name</p> <p>5 of that company?</p> <p>6 A. Informa is what I think the</p> <p>7 company is called, I-N-F-O-R-M-A, I think.</p> <p>8 Q. And do you know where they're</p> <p>9 headquartered?</p> <p>10 A. I do not.</p> <p>11 Q. Are they in Europe or do you</p> <p>12 just not have any idea?</p> <p>13 A. I do not know.</p> <p>14 Q. How were you contacted to</p> <p>15 present at that seminar?</p> <p>16 A. I do not know.</p> <p>17 Q. Did someone recommend you to be</p> <p>18 a speaker at that seminar?</p> <p>19 A. I do not know.</p> <p>20 Q. Were you told what topic they</p> <p>21 wanted you to speak about at that seminar?</p> <p>22 A. I do not know.</p> <p>23 Q. Do you know how they got your</p> <p>24 name as a potential speaker?</p> <p>Page 159</p> <p>1 A. No, I do not know.</p> <p>2 Q. Had you ever spoken at an</p> <p>3 Informa seminar before?</p> <p>4 A. I had not.</p> <p>5 Q. Had you ever attended an</p> <p>6 Informa seminar before?</p> <p>7 A. I had not.</p> <p>8 Q. Did Informa pay for your travel</p> <p>9 to the seminar and your hotel?</p> <p>10 A. Yes, I think so.</p> <p>11 Q. Was this the first time that</p> <p>12 you spoke publicly regarding nitrosamine</p> <p>13 impurities in pharmaceuticals?</p> <p>14 A. Yes, I do think so.</p> <p>15 Q. Did Informa provide you any</p> <p>16 information upon which to base your</p> <p>17 presentation on?</p> <p>18 A. No, I do not think so.</p> <p>19 Q. Now, referring you to the next</p> <p>20 sentence in the e-mail, which reads: The</p> <p>21 rationale to use BMDL10 instead of TD50 is</p> <p>22 [as read] I very nicely explained in the</p> <p>23 Valsartan Art 31 uAR 19.9.18, open parens, to</p> <p>24 MAHs, close parens, document, copy attached.</p>	<p>Page 160</p> <p>1 Are you aware of the existence</p> <p>2 of that document?</p> <p>3 A. That does not ring a bell. I</p> <p>4 do not know that title for that document.</p> <p>5 Q. Then the next sentence reads:</p> <p>6 I believe this was written by George Johnson</p> <p>7 of Swansea University, who is the super</p> <p>8 expert of this field, and thus, I had</p> <p>9 recommended him as an external expert.</p> <p>10 Do you see that?</p> <p>11 A. I do see that.</p> <p>12 Q. Do you know of a document that</p> <p>13 explained the rationale to use BMDL10 instead</p> <p>14 of TD50 that was written by you that would</p> <p>15 have been in existence as of November 14th,</p> <p>16 2018?</p> <p>17 A. I do not know beyond the</p> <p>18 PowerPoint presentation from that Informa</p> <p>19 meeting.</p> <p>20 Q. Now, that meeting was in June</p> <p>21 of 2018, correct? And this e-mail is dated</p> <p>22 November of 2018.</p> <p>23 Did you have any contact with</p> <p>24 Ralph Nudelman between the June of 2018</p> <p>Page 161</p> <p>1 conference and the date of this e-mail?</p> <p>2 A. I don't think so.</p> <p>3 Q. As of the date of this e-mail,</p> <p>4 had you been contacted by Teva or GT to serve</p> <p>5 as an external expert for Teva?</p> <p>6 A. I can't recall.</p> <p>7 Q. Do you see the next paragraph</p> <p>8 in this e-mail that begins with "The BMDL10"?</p> <p>9 A. I see that.</p> <p>10 Q. Would you please read that</p> <p>11 paragraph?</p> <p>12 A. The BMDL10 represents an</p> <p>13 estimate of the lowest dose which is 95%</p> <p>14 certain to cause no more than 10 -- than a</p> <p>15 10% cancer incidence in rodents, as the point</p> <p>16 of departure for the calculation of excess</p> <p>17 cancer risk.</p> <p>18 Q. Is that a sentence that was</p> <p>19 written by you? Do you recognize that</p> <p>20 sentence?</p> <p>21 A. That's a sentence that could</p> <p>22 relate to many documents on the BMDL</p> <p>23 calculation.</p> <p>24 Q. Do you agree with that</p>
--	--

<p style="text-align: right;">Page 162</p> <p>1 sentence?</p> <p>2 A. I do agree with that sentence.</p> <p>3 Q. Does it look familiar to you?</p> <p>4 A. Looks familiar in the fact that</p> <p>5 it's in most publications on this topic, a</p> <p>6 very similar statement to that.</p> <p>7 Q. Have you written a statement</p> <p>8 similar to that?</p> <p>9 A. Within my publications you will</p> <p>10 see statements very similar to that.</p> <p>11 Q. And then with regard to the</p> <p>12 second sentence, which reads: The BMDL10 is</p> <p>13 considered to represent a more realistic</p> <p>14 point of departure for risk estimations in</p> <p>15 low-exposure scenarios more realistic point</p> <p>16 of departure for risk estimations in</p> <p>17 low-exposure scenarios than the TD50 value.</p> <p>18 Does that sentence look</p> <p>19 familiar to you?</p> <p>20 A. With the same regard, that</p> <p>21 looks similar to any publication along these</p> <p>22 lines.</p> <p>23 Q. Could those two sentences have</p> <p>24 come off your PowerPoints from the 2018</p>	<p style="text-align: right;">Page 164</p> <p>1 e-mail?</p> <p>2 A. This is American format, but I</p> <p>3 think it's the 26th of the 3rd, 2019.</p> <p>4 Q. So it would be March 26th,</p> <p>5 2019?</p> <p>6 A. Looks that way.</p> <p>7 Q. Do you remember getting an</p> <p>8 e-mail from Ralph Nudelman in March of 2019?</p> <p>9 A. I don't remember specifically,</p> <p>10 but many experts send me on publications that</p> <p>11 they deem relevant.</p> <p>12 Q. At the time that you got this</p> <p>13 e-mail from Ralph Nudelman, were you doing</p> <p>14 consulting work for Teva with regard to the</p> <p>15 nitrosamine contamination of valsartan</p> <p>16 products?</p> <p>17 A. I cannot recall.</p> <p>18 Q. Well, did you have any e-mail</p> <p>19 exchanges typically with Ralph Nudelman</p> <p>20 before you were hired as an external</p> <p>21 consultant for the company?</p> <p>22 A. Not that I can recall.</p> <p>23 Q. So your e-mail communications</p> <p>24 with him began after you were hired to work</p>
<p style="text-align: right;">Page 163</p> <p>1 seminar that you did in Berlin?</p> <p>2 MS. LOCKARD: Objection, form,</p> <p>3 speculation.</p> <p>4 A. I do not know, and I don't want</p> <p>5 to speculate.</p> <p>6 MS. BOGDAN: If we could please</p> <p>7 pull up the next exhibit, which is</p> <p>8 Teva document that ends in 492386.</p> <p>9 (Whereupon, Deposition Exhibit</p> <p>10 Johnson-8, E-mail(s) re: Snodin &</p> <p>11 Elder Commentary,</p> <p>12 TEVA-MDL2875-00492386, was marked for</p> <p>13 identification.)</p> <p>14 THE STENOGRAPHER: That's</p> <p>15 Exhibit 8.</p> <p>16 BY MS. BOGDAN:</p> <p>17 Q. And please let me know once</p> <p>18 you're able to visualize that.</p> <p>19 A. I'm able to visualize that on</p> <p>20 Golkow.</p> <p>21 Q. Okay. And that's an e-mail</p> <p>22 from Ralph Nudelman to you, correct?</p> <p>23 A. That's correct.</p> <p>24 Q. And what is the date of that</p>	<p style="text-align: right;">Page 165</p> <p>1 as an external consultant for Teva, correct?</p> <p>2 MS. LOCKARD: Objection, form.</p> <p>3 A. I have e-mails from many</p> <p>4 experts, and they send me information, but I</p> <p>5 would not have had information around details</p> <p>6 of this, of the consultancy, prior to</p> <p>7 starting up the official consultancy.</p> <p>8 BY MS. BOGDAN:</p> <p>9 Q. So it's your testimony that</p> <p>10 this e-mail would have been after you had</p> <p>11 been approached and agreed to serve as a</p> <p>12 consultant for Teva?</p> <p>13 MS. LOCKARD: Objection, form,</p> <p>14 misstates the testimony.</p> <p>15 A. I don't know. It could have</p> <p>16 come after. It could have come before. I do</p> <p>17 not know.</p> <p>18 BY MS. BOGDAN:</p> <p>19 Q. Did you have Ralph Nudelman's</p> <p>20 e-mail address before you were hired as a</p> <p>21 consultant for Teva?</p> <p>22 A. I don't think so. I'd never</p> <p>23 worked with him previously.</p> <p>24 Q. Was there any type of agreement</p>

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1 between yourself and Teva regarding working
 2 as an expert for them?
 3 MS. LOCKARD: Object to form,
 4 vague.
 5 A. I do not know that information.
 6 BY MS. BOGDAN:
 7 Q. Was there any type of a
 8 retainer agreement or writing between you or
 9 Swansea Innovations and Teva that set forth
 10 the nature of the type of work you were going
 11 to do and how much you were going to charge
 12 to do it?
 13 MS. LOCKARD: Objection, form,
 14 ambiguous.
 15 A. I don't think so.
 16 BY MS. BOGDAN:
 17 Q. How would we determine the date
 18 on which you started to do consulting work
 19 for Teva?
 20 MS. LOCKARD: Objection, form,
 21 ambiguous.
 22 A. I do not know the start date.
 23 BY MS. BOGDAN:
 24 Q. Do you have any record, whether

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1 it be on a calendar or otherwise, that would
 2 indicate when you started doing consulting
 3 work for Teva?
 4 A. I do not have that information,
 5 no.
 6 Q. Would Swansa -- or Swansea,
 7 excuse me, Innovations, have any such written
 8 record as to when you began doing consulting
 9 work for Teva?
 10 MS. LOCKARD: Objection, form,
 11 ambiguous.
 12 A. I do not know.
 13 BY MS. BOGDAN:
 14 Q. Do you notify Swansea
 15 Innovations if you have been approached and
 16 have agreed to do consulting work?
 17 A. I do, and they generate these
 18 invoices.
 19 Q. Well, that's after you've done
 20 the work, correct?
 21 A. Yes.
 22 Q. What about initially when
 23 you're agreed to do the work, do you do any
 24 type of notification to Swansea Innovations

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1 to let that subsidiary of the university know
 2 that you are going to be doing consulting
 3 work for a particular company?
 4 A. Yes, and they will -- yes.
 5 Q. How do you go about notifying
 6 them?
 7 A. I will e-mail Swansea
 8 Innovations with that information.
 9 Q. Do you have a copy of the
 10 e-mail that you sent to Swansea Innovations
 11 with the information that you had been
 12 approached by Teva to do consulting work?
 13 MS. LOCKARD: Objection, form,
 14 ambiguous.
 15 A. I do not have that e-mail.
 16 BY MS. BOGDAN:
 17 Q. Would Swansea keep a copy of
 18 that e-mail?
 19 A. I do not know.
 20 Q. What is the purpose of sending
 21 Swansea Innovations that e-mail?
 22 A. To initiate the consultancy
 23 documentation.
 24 Q. And what is the consultancy

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1 documentation particularly?
 2 A. Conflict of interest --
 3 nondisclosure agreements, often, are those
 4 forms. Mostly those -- mostly nondisclosure
 5 agreements, if they're required by the
 6 company.
 7 Q. Was there a nondisclosure
 8 agreement required by Mylan -- by Teva?
 9 A. Not that I'm aware of at this
 10 time for this first invoice.
 11 Q. Now, this first invoice is for
 12 91 hours of time. How many hours a week did
 13 you work on this project approximately, back
 14 in the fall of 2020?
 15 A. I do not know. It wasn't a
 16 strict number of hours per week.
 17 Q. The 91 hours of work that's
 18 billed for on the November 9th, 2020 e-mail,
 19 what months of 2020 was that work done in?
 20 A. I do not know.
 21 Q. Was some of it done in October
 22 of 2020?
 23 A. That would be an assumption,
 24 but could be correct.

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1 MS. LOCKARD: When we get to a
2 stopping point, let's take a break,
3 because I know we've been going for an
4 hour and a half or so.
5 BY MS. BOGDAN:
6 Q. Well, would the 91 hours of
7 work have been done in November of 2020 in
8 total, like all of it done in November of
9 2020?
10 A. No, that did not happen.
11 Q. So we know some of the work
12 occurred before November of 2020; is that
13 fair?
14 A. That is fair.
15 Q. Did you do any work consulting
16 for Teva during the summer of 2020?
17 MS. LOCKARD: Objection, form,
18 ambiguous.
19 A. I would have been reading the
20 regulatory documents related to this issue
21 and to my consultancy with GT and Teva during
22 months previous to October.
23 BY MS. BOGDAN:
24 Q. Can you give me an estimation

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1 of the number of months previous to October
2 of 2020 that you would have been doing work
3 reading regulatory documents in connection
4 with your consultant work for Teva?
5 MS. LOCKARD: Objection, form,
6 ambiguous.
7 A. I couldn't give you an accurate
8 assumption, no.
9 MS. LOCKARD: So I'd like to
10 take a break now. So, Rosemarie, what
11 would you like to do about a lunch
12 break? Because we have food here
13 that's been sitting.
14 MS. BOGDAN: Oh, I wasn't aware
15 because I'm obviously not there.
16 If -- there's just one more document
17 on this topic that I wanted to show,
18 so I'm happy to take a break, but it
19 makes sense to just do this one more,
20 and then take a lunch break. It's
21 just a one-page document.
22 MS. LOCKARD: Okay. If there's
23 just a couple of questions.
24 MS. BOGDAN: Okay. It's

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1 really -- it's just a one-page
2 document, and you'll see it when I put
3 it up. It's Teva 425960.
4 (Whereupon, Deposition Exhibit
5 Johnson-9, E-mail(s) re: Snodin &
6 Elder Commentary,
7 TEVA-MDL2875-00425960, was marked for
8 identification.)
9 THE STENOGRAPHER: And that's
10 Exhibit 9.
11 BY MS. BOGDAN:
12 Q. And, Doctor, when you can see
13 that, please let me know.
14 A. Okay. Not yet. Still not
15 there.
16 Q. It's only one page, so it
17 shouldn't take too long.
18 A. But it's not here.
19 I've got it.
20 Q. Okay. Do you see that? It's
21 an e-mail?
22 A. I see that.
23 Q. And what is it dated?
24 A. 26th of the 3rd, 2019.

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1 Q. Okay. And is that e-mail from
2 you?
3 A. That is my e-mail address,
4 g.johnson@swansea.ac.uk.
5 Q. And who is the e-mail to?
6 A. To Raphael Nudelman with cc'd
7 in other people, Brian McCormick and Rachel
8 Gallagher.
9 Q. And are they all, to your
10 knowledge, affiliated with Teva
11 Pharmaceuticals?
12 A. Yes, as far as my knowledge
13 from their e-mail addresses, they look
14 associated with Teva.
15 Q. And do you remember sending
16 this e-mail?
17 A. I do not remember sending this
18 e-mail, but if someone sends me a document,
19 the subject for this is Snodin & Elder, it's
20 polite to reply.
21 Q. At the time that you replied to
22 this e-mail, were you doing work for Teva as
23 a consultant?
24 MS. LOCKARD: Objection, form,

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1 ambiguous.
 2 A. I do not know. I do not think
 3 so.
 4 BY MS. BOGDAN:
 5 Q. And why don't you think so?
 6 A. The nature of this e-mail was
 7 passing on a commentary on this topic.
 8 Q. What about the nature of the
 9 e-mail passing on commentary on this topic
 10 makes you think you weren't doing consulting
 11 work yet?
 12 A. Because the previous e-mail
 13 that this was replied to that you showed me
 14 previously was a one-sentence passing me on
 15 this commentary with no further information,
 16 which you could assume would be given if
 17 consultancy and detailed analysis of the
 18 situation would have started.
 19 Q. Meaning the shortness of the
 20 redacted portion? Is that what you're
 21 referring to?
 22 A. Of the previous e-mail that
 23 looks like related to this one. This is
 24 Snodin & Elder commentary. The previous

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1 exhibit you showed me was what this is
 2 replying to, as far as I'm aware.
 3 Q. Did you keep copies of your
 4 e-mails back and forth with Raphael Nudelman?
 5 MS. LOCKARD: Objection, form.
 6 (Clarification requested by the
 7 stenographer.)
 8 A. I do not think so.
 9 MS. BOGDAN: All right. Did
 10 you want to take a break, Victoria,
 11 for lunch?
 12 MS. LOCKARD: Yes. It's 1:20
 13 in the afternoon here, so let's do
 14 that.
 15 THE VIDEOGRAPHER: Going off
 16 the record. The time is 1:20 p.m.
 17 (Recess taken, 1:20 p.m. to
 18 2:03 p.m. BST)
 19 THE VIDEOGRAPHER: Back on the
 20 record. The time is 2:03 p.m.
 21 BY MS. BOGDAN:
 22 Q. Good afternoon. Can you hear
 23 me?
 24 A. Good afternoon.

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1 Q. Okay. Good.
 2 Now, I have previously asked
 3 you about being familiar with the journal
 4 Environmental and Molecular Mutagenesis
 5 before we took the break.
 6 A. Yes, you had previously asked
 7 me about that.
 8 Q. That's right. And you have
 9 actually published several articles in that
 10 journal, correct?
 11 A. That is correct.
 12 Q. How did you first come to
 13 publish in that journal?
 14 A. Potentially as a coauthor on a
 15 publication with another coauthor, and then
 16 realizing it was a suitable journal.
 17 Potentially as a coauthor.
 18 Q. Do you know the first journal
 19 that you published as a coauthor in
 20 Environmental and Molecular Mutagenesis?
 21 A. I do not.
 22 MS. BOGDAN: Why don't we
 23 please bring up exhibit C2, which
 24 should be entitled Mutation as a

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1 Toxicological Endpoint for Regulatory
 2 Decision-Making.
 3 (Whereupon, Deposition Exhibit
 4 Johnson-10, Mutation as a
 5 Toxicological Endpoint for Regulatory
 6 Decision-Making, by Heflich et al, was
 7 marked for identification.)
 8 THE WITNESS: I don't have it
 9 yet. Oh. Here.
 10 A. I have that on my desktop now.
 11 BY MS. BOGDAN:
 12 Q. Okay. We don't seem to have it
 13 up on our screen. I don't know if the other
 14 people on Zoom can see it, but I don't.
 15 There we go. I think that's the first time
 16 it's hit your screen before our screen.
 17 A. Yay.
 18 TRIAL TECHNICIAN: Double
 19 click.
 20 BY MS. BOGDAN:
 21 Q. All right. Now, with regard to
 22 when you're a coauthor on a publication, do
 23 you have a choice as to which journal the
 24 publication is submitted to for publication

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1 or is that the primary author's call usually,
2 in your practice?
3 A. It can go any way. There can
4 be any decision made. There's no standard
5 process for deciding on a journal article, a
6 journal to target.
7 Q. For example, with this
8 particular journal article that's been marked
9 as Exhibit 10, was there a discussion between
10 the coauthors as to where it would be
11 submitted for publication?
12 A. I cannot remember. I see a big
13 link with these coauthors in that journal.
14 Q. Okay. And when you say you see
15 a big link with these coauthors in that
16 journal, what makes you say that?
17 A. Bob Heflich, Robert Heflich
18 from FDA, used to be an editor on it.
19 Bhaskar Gollapudi is an editor on it, the
20 current editor. Paul White was a lead editor
21 as well, and Francesco Marchetti, both of
22 those from Health Canada. I'm unsure with
23 Kristine Witt, whether she's been involved on
24 the editorial board. So that's why I make

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1 that statement.
2 Q. And was Bhaskar Gollapudi the
3 editor-in-chief at the time that this
4 particular article was published back in
5 2019?
6 A. I do not know, either him or
7 Francesco Marchetti.
8 Q. How did you first meet Bhaskar
9 Gollapudi?
10 A. I met him at the HESI Genetic
11 Toxicology Technical Committee. That's where
12 I met him.
13 Q. And did he serve on that
14 committee with you?
15 A. He did at that time, yes.
16 Q. And what time period are we
17 talking about?
18 A. Towards generation of our
19 publication in 2013, so the lead-up to
20 generate that publication.
21 Q. So that didn't come out as
22 clearly with the connection.
23 So sometime working up to the
24 2013 publication?

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1 A. Correct.
2 Q. Is that what you --
3 A. Correct, yes.
4 Q. Okay. What 2013 publication
5 are you referring to?
6 A. I'm going to look at my CV for
7 the exact. Yep.
8 Found it. There's plenty of
9 coauthors, Gollapudi, et al.; we include
10 numerous FDA and Health Canada, all those
11 authors. So many authors on that.
12 Gollapudi, et al. 2013, Environmental
13 Molecular Mutagenesis and so on.
14 So I'll read the title.
15 Quantitative Approaches for Assessing
16 Dose-Response Relationships in Genetic
17 Toxicology Studies.
18 Q. And is that the first study
19 that you coauthored with Gollapudi?
20 A. I think it is, yes.
21 Q. And what company does Gollapudi
22 work with or for, if you know?
23 A. At the current time?
24 Q. In -- well, is there a

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1 difference between now and back in 2013?
2 Who did he work for in 2013, if
3 you know?
4 A. One of two, Exponent or Dow,
5 Dow Chemical. Either Exponent or Dow
6 Chemical.
7 Q. He worked for Dow Chemical
8 before he worked for Exponent?
9 A. Yes, he did, and may have had a
10 job in between. Those are the two major jobs
11 that I'm aware that he's undertaken, the
12 companies that he's worked with.
13 Q. And currently does he work with
14 Exponent?
15 A. Yes, I think he does.
16 Q. And the title of this
17 commentary is Mutation As a Toxicological
18 Endpoint for Regulatory Decision-Making,
19 correct?
20 A. Yes, I see that's correct.
21 Q. Okay. And you are the second
22 noted author on this publication, correct?
23 A. That is correct.
24 Q. Did you note on this

<p style="text-align: right;">Page 182</p> <p>1 publication that was published in October of 2 2019 any conflicts of interest? 3 A. May I look at the statement? 4 I'm not sure. I don't think conflicts of 5 interest were stated, that there was any 6 conflict of interest for this publication. 7 Q. At the time of this 8 publication, you were working as a consultant 9 for Teva in connection with this litigation; 10 isn't that correct? 11 MS. LOCKARD: Objection, form, 12 ambiguous. 13 A. My consultancy with Teva and 14 GT, I did some of that in 2020, and we were 15 preparing this manuscript for many years. 16 BY MS. BOGDAN: 17 Q. But at the time of its 18 publication, you were doing consulting work 19 for Teva, correct? 20 MS. LOCKARD: Objection, form, 21 ambiguous. 22 A. I do not know. It says 23 published online, 10th of October 2019. 24 2019? I do not know if that's the case.</p>	<p style="text-align: right;">Page 184</p> <p>1 THE STENOGRAPHER: Yes. 2 THE WITNESS: Is that question 3 to me? 4 MS. BOGDAN: Exhibit 11? 5 THE STENOGRAPHER: Yes. 6 BY MS. BOGDAN: 7 Q. If I could direct your 8 attention to the second page of the exhibit, 9 under Conflict of Interest Declaration at the 10 bottom of the page. 11 A. Okay. I can see that. 12 Q. Can you please read the first 13 sentence of the Conflict of Interest 14 Declaration? 15 A. At the time of submission, EMM 16 policy requires that each and every author 17 reveal any financial interests or 18 connections, direct or indirect, or other 19 situations that might raise the question of 20 bias in the work reported or the conclusions, 21 implications, or opinions stated. 22 Q. Does that sentence say anything 23 about it being a review article versus 24 original work?</p>
<p style="text-align: right;">Page 183</p> <p>1 BY MS. BOGDAN: 2 Q. But you did not disclose any 3 conflict of interest in this publication, 4 correct? 5 A. Correct. This sort of 6 publication would be more of a review 7 concept-type document, and conflict of 8 interest, from my interpretation, better 9 linked to new opinions based on data. 10 MS. BOGDAN: If you could 11 please pull up exhibit entitled 12 Environmental and Molecular 13 Mutagenesis, Author Guidelines, 14 please. 15 (Whereupon, Deposition Exhibit 16 Johnson-11, EMM Author Guidelines, 17 Conflict of Interest Declaration, was 18 marked for identification.) 19 THE STENOGRAPHER: That's 20 Exhibit 11. 21 A. Okay. Yeah, I have those in 22 front of me. 23 MS. BOGDAN: And have we marked 24 this as an exhibit?</p>	<p style="text-align: right;">Page 185</p> <p>1 A. It does not state that, no. 2 Q. Please read the second sentence 3 of the Conflict of Interest Declaration. 4 A. These include pertinent 5 commercial or other sources of funding for 6 the individual author or for the associated 7 departments or organizations, personal 8 relationships, or direct academic 9 competition. 10 Q. Were you paid for your work 11 consulting for Teva? 12 A. I'm paid by GT when consulting 13 with Teva and GT. 14 Q. If we could go back to the 15 first page of Exhibit 10, please. 16 A. I'm on that page. 17 Q. The decisions -- or excuse me, 18 the opinions that you're giving in this 19 matter, don't they deal with toxicological 20 endpoints for regulatory decision-making? 21 A. The focus is on genetic 22 toxicological endpoints, including mutation 23 and including chromosomal data for that 24 decision-making, and does not include making</p>

<p style="text-align: right;">Page 186</p> <p>1 the decision based on cancer bioassay data.</p> <p>2 Q. However, your report and your</p> <p>3 opinions that you've given in this case</p> <p>4 include evaluation of mutations for</p> <p>5 regulatory decision-making, do they not?</p> <p>6 A. They include evaluation of</p> <p>7 mutations in order to define the mechanism,</p> <p>8 and this document does not define the</p> <p>9 mechanism. This document is around</p> <p>10 discussing -- using the metrics from the</p> <p>11 in vivo mutation data to define the point of</p> <p>12 departure for risk assessment, which is</p> <p>13 different.</p> <p>14 Q. In this litigation, are you not</p> <p>15 proposing PEDs [sic] for NDMA and NDEA?</p> <p>16 A. In this litigation, I'm</p> <p>17 proposing PDEs for NDEA and NDMA based on</p> <p>18 cancer bioassay dose response data, yes.</p> <p>19 Q. But proposing PEDs, which</p> <p>20 are -- what does PED stand for, just so that</p> <p>21 the record is clear?</p> <p>22 A. It's PDE. It's permitted daily</p> <p>23 exposure.</p> <p>24 Q. And with regard to the opinions</p>	<p style="text-align: right;">Page 188</p> <p>1 about. My paper is about defining those from</p> <p>2 the cancer bioassay data and applying them to</p> <p>3 this instance.</p> <p>4 Q. I'm not asking about the paper</p> <p>5 at this point.</p> <p>6 Do you agree that your opinion</p> <p>7 in this case involves regulatory</p> <p>8 decision-making and suggesting daily exposure</p> <p>9 limits?</p> <p>10 A. My opinion is based on defining</p> <p>11 a human exposure limit that can be applied in</p> <p>12 order to define whether a human is at</p> <p>13 increased risk of cancer.</p> <p>14 Q. So this case involves defining</p> <p>15 human exposure limits, correct?</p> <p>16 A. Correct, but from cancer data</p> <p>17 and not from mutation data, which is the</p> <p>18 entire premise of the commentary which we're</p> <p>19 discussing.</p> <p>20 Q. Don't you cite to your 2021</p> <p>21 Permitted Daily Exposure Limits for</p> <p>22 Noteworthy Nitrosamine paper as support for</p> <p>23 your decision -- or your opinions in this</p> <p>24 case?</p>
<p style="text-align: right;">Page 187</p> <p>1 that you're offering for permitted daily</p> <p>2 exposures, that goes to regulatory concerns</p> <p>3 with regard to how much NDMA or NDEA can be</p> <p>4 in a pharmaceutical, does it not?</p> <p>5 A. It does not, because the risk</p> <p>6 assessment I've carried out in my report is</p> <p>7 entirely around PDE metrics from the cancer</p> <p>8 bioassay data, and this commentary is to</p> <p>9 propose that in the future we could do that</p> <p>10 calculation on mutation data, but that's not</p> <p>11 what is done in my report, in my risk</p> <p>12 assessment here. So they are independent and</p> <p>13 different approaches.</p> <p>14 Q. So you're actually</p> <p>15 distinguishing between mutation data and</p> <p>16 carcinogenesis data? Is that my</p> <p>17 understanding?</p> <p>18 A. That is your understanding,</p> <p>19 with regard to using that data for a PDE</p> <p>20 calculation.</p> <p>21 Q. Do you agree that your opinion</p> <p>22 involves regulatory decision-making and</p> <p>23 suggesting daily exposure limits?</p> <p>24 A. That's not what this paper is</p>	<p style="text-align: right;">Page 189</p> <p>1 A. From my report submitted as my</p> <p>2 risk assessment for this, I did cite my PDE</p> <p>3 publication, and the decisions and opinions</p> <p>4 are based on the cancer-derived PDE metrics</p> <p>5 and not from the mutation-derived PDE</p> <p>6 metrics. They are very independent.</p> <p>7 Q. So with regard to your opinions</p> <p>8 that you're offering in this case, you are</p> <p>9 not in any way relying on the mutation PDE</p> <p>10 values that you set forth in your 2021</p> <p>11 publication entitled Permitted Daily Exposure</p> <p>12 Limits for Noteworthy Nitrosamines?</p> <p>13 A. That's correct. My reliance</p> <p>14 here is on the cancer-derived PDE metrics</p> <p>15 where the mutations were presented in that</p> <p>16 publication for other reasons.</p> <p>17 Q. And what were the other reasons</p> <p>18 that the mutations were presented in the 2021</p> <p>19 publication but are not presented in your</p> <p>20 report in this litigation?</p> <p>21 A. My area of research, including</p> <p>22 what we've discussed today, is -- and based</p> <p>23 on this paper, which you kindly put forward,</p> <p>24 the mutation toxicological endpoint for --</p>

<p style="text-align: right;">Page 190</p> <p>1 (audio malfunction) --</p> <p>2 (Clarification requested by the</p> <p>3 stenographer.)</p> <p>4 A. -- for regulatory</p> <p>5 decision-making. So the mutation PDEs in my</p> <p>6 2021 publication talk to this and say in the</p> <p>7 future, could we use mutation-derived PDEs,</p> <p>8 and if we did, what would they look like</p> <p>9 compared to cancer-derived PDEs.</p> <p>10 Because in addition to these</p> <p>11 nitrosamines that we're looking at today,</p> <p>12 many nitrosamines do not have reliable cancer</p> <p>13 bioassay data. So if we could do the risk</p> <p>14 assessment on a more sensitive endpoint where</p> <p>15 we admit that we would have a lower PDE,</p> <p>16 would we still protect the human population.</p> <p>17 So that's the premise of adding</p> <p>18 those mutation-derived ones in the conceptual</p> <p>19 format of that discussion in support of the</p> <p>20 decision, the ideas here.</p> <p>21 But for the actual application</p> <p>22 to a risk assessment, we've got the cancer</p> <p>23 data. It's very strong cancer data, and we</p> <p>24 use that for our human health risk assessment</p>	<p style="text-align: right;">Page 192</p> <p>1 data to derive PDEs. And in the paper, we</p> <p>2 present them in comparison to cancer-derived</p> <p>3 PDEs to see if they would still provide a</p> <p>4 concentration similar to the PDE or we</p> <p>5 predicted below the PDE because mutation</p> <p>6 occurs at a lower concentration in a cancer</p> <p>7 as supported by this. And we're working on</p> <p>8 future case studies along that line.</p> <p>9 BY MS. BOGDAN:</p> <p>10 Q. Okay. We will go back and talk</p> <p>11 more about the 2021 publication later.</p> <p>12 With regard to the exhibit that</p> <p>13 is still, I believe, up on your screen --</p> <p>14 A. Sorry. Okay.</p> <p>15 Q. -- which is the Mutation as a</p> <p>16 Toxicological Endpoint for Regulatory</p> <p>17 Decision-Making?</p> <p>18 A. It is no longer on my screen.</p> <p>19 Could you inform me which exhibit it is</p> <p>20 again, please?</p> <p>21 Q. I believe it was exhibit -- was</p> <p>22 it 11?</p> <p>23 THE STENOGRAPHER: 11 was the</p> <p>24 last one.</p>
<p style="text-align: right;">Page 191</p> <p>1 and not the mutation data for the human</p> <p>2 health risk assessment in this instance.</p> <p>3 BY MS. BOGDAN:</p> <p>4 Q. However, in your 2021 research</p> <p>5 article, the one that we've been speaking</p> <p>6 about, Permitted Daily Exposure Limits for</p> <p>7 Noteworthy Nitrosamines, you did go about</p> <p>8 calculating PDEs for both NDMA and NDEA for</p> <p>9 cancer and mutation, correct?</p> <p>10 A. That is correct, and we</p> <p>11 critique the mutation-derived PDEs and</p> <p>12 provide information about how future datasets</p> <p>13 could look and further concepts around</p> <p>14 adjustment factors in order to apply those in</p> <p>15 a future setting in a more conceptual way.</p> <p>16 Q. And when you say in a future</p> <p>17 setting in a more conceptual way, meaning</p> <p>18 despite the fact you calculated these</p> <p>19 mutation PDEs in the article, you did it only</p> <p>20 for conceptual purposes?</p> <p>21 MS. LOCKARD: Objection, form,</p> <p>22 misstates.</p> <p>23 A. We did it in support of this</p> <p>24 idea that you could, in theory, use mutation</p>	<p style="text-align: right;">Page 193</p> <p>1 TRIAL TECHNICIAN: It was</p> <p>2 Exhibit 10.</p> <p>3 MS. BOGDAN: 10.</p> <p>4 TRIAL TECHNICIAN: Yes.</p> <p>5 A. I have it now.</p> <p>6 BY MS. BOGDAN:</p> <p>7 Q. Would this article pertain to</p> <p>8 Teva Pharmaceuticals, potentially in their</p> <p>9 work as a pharmaceutical company?</p> <p>10 A. This article relates to that</p> <p>11 concept around using mutation data for risk</p> <p>12 assessment in future studies, so not linked</p> <p>13 to Teva. To the whole field of analysis,</p> <p>14 could we use mutation data in future risk</p> <p>15 assessments in the absence of cancer data.</p> <p>16 Q. When you're talking about using</p> <p>17 mutation data, that could be used in the</p> <p>18 pharmaceutical industry, correct?</p> <p>19 A. That could be correct, and it</p> <p>20 could also be applied to other industries and</p> <p>21 regulatory arenas too.</p> <p>22 Q. If we could please bring up the</p> <p>23 next exhibit, which is an Environmental and</p> <p>24 Molecular Mutagenesis commentary entitled</p>

<p style="text-align: right;">Page 194</p> <p>1 Quantitative Interpretation of Genetic 2 Toxicity Dose. 3 (Whereupon, Deposition Exhibit 4 Johnson-12, Quantitative 5 Interpretation of Genetic Toxicity 6 Dose-Response Data for Risk Assessment 7 and Regulatory Decision-Making: 8 Current Status and Emerging 9 Priorities, by White et al, was marked 10 for identification.) 11 THE STENOGRAPHER: Chris, I'm 12 showing that as 12? 13 TRIAL TECHNICIAN: That is 14 correct. 15 BY MS. BOGDAN: 16 Q. If we could go to the first 17 page of the commentary, please. 18 A. I think I have this. Is this 19 the one downloaded from ResearchGate? 20 Q. Yes, I believe so, Doctor, and 21 if you could go to the second page of the 22 exhibit. 23 A. Yeah. 24 Q. Is this a commentary that you</p>	<p style="text-align: right;">Page 196</p> <p>1 et al, was marked for identification.) 2 BY MS. BOGDAN: 3 Q. Is this another research 4 article that you're a coauthor on? 5 A. This has yet to appear. Are we 6 on Exhibit 13? Okay, I have it. 7 Q. Is the article up for you now, 8 Doctor? 9 A. Yes, I have it now. 10 Q. Is this an article that you 11 were a coauthor on? 12 A. Yes, it's an article I'm a 13 coauthor on. 14 Q. Okay. And who are your 15 coauthors on this article? 16 A. So Bhaskar Gollapudi, who we've 17 talked about from Exponent. Abby Li from 18 Exponent, Steave Su from Exponent, myself, 19 Richard Reiss from Exponent and Richard 20 Albertini, also called Dick Albertini, from 21 Burlington, Vermont, University of Vermont 22 College of Medicine. 23 Q. Now, when was this research 24 article accepted? I believe it's at the top</p>
<p style="text-align: right;">Page 195</p> <p>1 coauthored? 2 A. Yes, it is a commentary that I 3 coauthored with Health Canada experts. 4 Q. Does this commentary involve 5 concepts such as point of departure metrics 6 and benchmark doses? 7 A. It includes those concepts 8 entirely related to genetic toxicology data. 9 Q. Did you disclose any conflicts 10 of interest in this commentary? 11 A. I'm just searching to the 12 conflict of interest part. Apologies. 13 I cannot see conflict of 14 interest stated in this publication. 15 Q. If we could please go to the 16 next exhibit, which is going to be a research 17 article entitled Genotoxicity as the -- there 18 we go -- Toxicologically Relevant Endpoint to 19 Inform Risk Assessment. 20 (Whereupon, Deposition Exhibit 21 Johnson-13, Genotoxicity as a 22 toxicologically relevant endpoint to 23 inform risk assessment: A case study 24 with ethylene oxide, by Gollapudi</p>	<p style="text-align: right;">Page 197</p> <p>1 of the -- 2 A. Oh, excellent. 3 Q. -- page. 4 A. Accepted 4th of September 2020. 5 Q. And I see there are three dates 6 on the top, received, and then revised and 7 then accepted. 8 Could you describe that process 9 for me, please? 10 A. With a publication in line with 11 this one or any publication, you submit the 12 publication, it gets reviewed by external 13 reviewers, if you're lucky to get to that 14 stage. Those external reviewers will 15 critique the publication -- although at that 16 stage, it's not a publication; it's a 17 manuscript. Ask you -- they'll accept it, 18 they'll give minor revisions, major revisions 19 or reject. 20 Then you have a period where 21 you can amend your publication in line with 22 those reviewers' comments and editorial 23 comments. That can be a long process, 24 particularly in this example when it goes</p>

<p>Page 198</p> <p>1 over the summer, and then -- and then it's</p> <p>2 accepted and put on -- put online in the</p> <p>3 final publication.</p> <p>4 Q. So the accepted date is the</p> <p>5 publication data, essentially, for online?</p> <p>6 A. For online.</p> <p>7 Q. So this particular research</p> <p>8 article was published September 4th of 2020?</p> <p>9 A. Yes. The final accepted</p> <p>10 version was published then.</p> <p>11 Q. Did you disclose any conflicts</p> <p>12 of interest in this publication?</p> <p>13 A. In this publication, there was</p> <p>14 funding from the American Chemistry Council,</p> <p>15 and this was declared in the Conflict of</p> <p>16 Interest section.</p> <p>17 Q. Did you personally declare any</p> <p>18 conflict of interest or disclose that you</p> <p>19 were doing consulting work for Teva</p> <p>20 Pharmaceuticals?</p> <p>21 MS. LOCKARD: Objection, form,</p> <p>22 ambiguous.</p> <p>23 A. In this statement, the conflict</p> <p>24 of interest covers the authors with the</p>	<p>Page 200</p> <p>1 And the application of those</p> <p>2 datasets to create a PDE, as we've stated for</p> <p>3 cancer, is an accepted approach, and for</p> <p>4 genetic toxicology data, it's more a</p> <p>5 conceptual approach that's trying to gain</p> <p>6 momentum.</p> <p>7 So I see quite a major --</p> <p>8 distinguish a major difference between this</p> <p>9 and a risk assessment based on cancer</p> <p>10 bioassay data, as I've presented for GT and</p> <p>11 the clients.</p> <p>12 Q. Does this research article</p> <p>13 discuss calculating daily exposure values,</p> <p>14 yes or no?</p> <p>15 A. This article is used to</p> <p>16 calculate permitted daily exposure values</p> <p>17 from genetic toxicology data.</p> <p>18 Q. And this article also discusses</p> <p>19 using a benchmark dose analysis, does it not?</p> <p>20 A. This article also describes the</p> <p>21 use of the benchmark dose analysis on genetic</p> <p>22 toxicology data.</p> <p>23 Q. And this article also discusses</p> <p>24 point of departure values, does it not?</p>
<p>Page 199</p> <p>1 American Chemistry Council. In my opinion,</p> <p>2 this does not work to the -- this was not</p> <p>3 relevant or applicable to the risk assessment</p> <p>4 report that I was compiling and generating</p> <p>5 for Teva and GT.</p> <p>6 BY MS. BOGDAN:</p> <p>7 Q. Even though the research</p> <p>8 article discusses points of departure and</p> <p>9 daily exposure values, correct?</p> <p>10 A. With the same discussions that</p> <p>11 these were based on the genetic toxicology</p> <p>12 data.</p> <p>13 Q. But this research article is</p> <p>14 dealing with points of departure, daily</p> <p>15 exposure values, using PROAST software and</p> <p>16 doing benchmark dose analyses; is that not</p> <p>17 true?</p> <p>18 A. These analyses using PROAST and</p> <p>19 benchmark dose were on different datasets.</p> <p>20 They are called continuous datasets from</p> <p>21 genetic toxicology, carried out in a</p> <p>22 different way to when you do it on cancer</p> <p>23 bioassay data, which is contour datasets. So</p> <p>24 that calculation is different.</p>	<p>Page 201</p> <p>1 A. This article also discusses the</p> <p>2 use of point of departure values from genetic</p> <p>3 toxicology data.</p> <p>4 MS. BOGDAN: If you could</p> <p>5 please put up the next exhibit, which</p> <p>6 is a research article, The Use of</p> <p>7 Benchmark Dose Uncertainty</p> <p>8 Measurements.</p> <p>9 (Whereupon, Deposition Exhibit</p> <p>10 Johnson-14, The use of benchmark dose</p> <p>11 uncertainty measurements for robust</p> <p>12 comparative potency analyses, by</p> <p>13 Wheeldon et al, was marked for</p> <p>14 identification.)</p> <p>15 THE STENOGRAPHER: 14.</p> <p>16 A. Okay. It's arrived. It's</p> <p>17 loading. I can see it.</p> <p>18 BY MS. BOGDAN:</p> <p>19 Q. Is this another research</p> <p>20 article that you coauthored?</p> <p>21 A. This is another research</p> <p>22 article that I coauthored.</p> <p>23 Q. And again, in the Environmental</p> <p>24 and Molecular Mutagenesis journal?</p>

<p style="text-align: right;">Page 202</p> <p>1 A. Yes, that's correct.</p> <p>2 Q. And this research article,</p> <p>3 again, refers to benchmark dose methods,</p> <p>4 correct?</p> <p>5 A. This does refer to benchmark</p> <p>6 dose methods as the best statistical -- the</p> <p>7 best statistical approach for analyzing these</p> <p>8 sorts of data, yes.</p> <p>9 Q. And it does benchmark dose</p> <p>10 modeling, correct?</p> <p>11 A. This uses benchmark dose</p> <p>12 modeling on in vitro genetic toxicology data</p> <p>13 points, correct.</p> <p>14 Q. And did you disclose a conflict</p> <p>15 of interest in this publication based upon</p> <p>16 the fact that you were doing consulting work</p> <p>17 for --</p> <p>18 A. No, because it has even less</p> <p>19 relevance than the in vivo genetic toxicology</p> <p>20 BMDs that were generated. So these are</p> <p>21 in vitro BMD potency comparisons using the</p> <p>22 advanced statistical tool of benchmark dose.</p> <p>23 Q. With regard to the conflict of</p> <p>24 interest declaration that we previously put</p>	<p style="text-align: right;">Page 204</p> <p>1 calculating, benchmark dose, is -- or applies</p> <p>2 to both situations?</p> <p>3 A. The calculation is completely</p> <p>4 different if we're talking about benchmark</p> <p>5 dose. As I've suggested, the cancer bioassay</p> <p>6 data is a quantum calculation using a</p> <p>7 different part of the BMD tool, using</p> <p>8 completely different statistical modeling</p> <p>9 from what you do on continuous data for</p> <p>10 genetic toxicity data, which uses a different</p> <p>11 suite of models. So they're very</p> <p>12 distinguished, yes.</p> <p>13 Q. Aren't these articles favoring</p> <p>14 the benchmark dose method?</p> <p>15 A. Which articles are we talking</p> <p>16 about?</p> <p>17 Q. The article that's right up on</p> <p>18 the screen here, The Use of Benchmark Dose</p> <p>19 Uncertainty Measurements for Robust</p> <p>20 Comparative Potency Analyses.</p> <p>21 A. This publication -- okay?</p> <p>22 Q. I'm sorry.</p> <p>23 And the abstract. Can you read</p> <p>24 the first sentence in the abstract?</p>
<p style="text-align: right;">Page 203</p> <p>1 up, with the EMM policy requiring that each</p> <p>2 and every author reveal any financial</p> <p>3 interest or connections, direct or indirect,</p> <p>4 or other situations that might raise the</p> <p>5 question of bias in the work reported, or the</p> <p>6 conclusions, implications or opinions stated,</p> <p>7 is it your testimony that research articles</p> <p>8 that you are doing that specifically address</p> <p>9 benchmark dose, which is the analysis that</p> <p>10 you're doing in this litigation, are not</p> <p>11 relevant?</p> <p>12 A. If those benchmark dose</p> <p>13 analyses are on in vitro genetic toxicology</p> <p>14 data and in vivo genetic toxicology data,</p> <p>15 then they are not a conflict when I'm</p> <p>16 carrying out the risk assessment here on</p> <p>17 in vivo cancer bioassay data.</p> <p>18 Q. So you were making a</p> <p>19 distinction between in vivo genetic</p> <p>20 toxicology data and cancer bioassay data in</p> <p>21 whether or not you need to disclose a</p> <p>22 conflict of interest?</p> <p>23 A. I am making that distinction.</p> <p>24 Q. Even though what you're</p>	<p style="text-align: right;">Page 205</p> <p>1 A. The benchmark dose method is</p> <p>2 the favored approach for quantitative</p> <p>3 dose-response analysis where uncertainty</p> <p>4 measurements are delineated between the upper</p> <p>5 and lower confidence bounds, or confidence</p> <p>6 intervals.</p> <p>7 Q. Would you say that that</p> <p>8 research article is suggesting that the</p> <p>9 benchmark dose method is the preferred</p> <p>10 quantitative approach?</p> <p>11 A. For these in vitro datasets</p> <p>12 using the covariant analysis approach where</p> <p>13 you end up with these potency ranks, I would</p> <p>14 agree that this is -- BMD is the favored</p> <p>15 approach as related here.</p> <p>16 Q. And in this case, are you not</p> <p>17 also advocating that the benchmark dose</p> <p>18 method is the favored approach?</p> <p>19 A. With these in vitro data,</p> <p>20 this --</p> <p>21 Q. I'm not asking about in vitro</p> <p>22 data. I'm just asking if you're also</p> <p>23 advocating in this case that the benchmark</p> <p>24 dose method is the favored approach.</p>

<p style="text-align: right;">Page 206</p> <p>1 MS. LOCKARD: I'm going to 2 object with you arguing and 3 interrupting the witness. I've let it 4 go on a little bit, but he's entitled 5 to give his answer. If it's not the 6 question that you meant to ask, you 7 can ask it again, but please don't cut 8 the witness off. 9 Go ahead. 10 THE WITNESS: Could you please 11 ask that question again? 12 BY MS. BOGDAN: 13 Q. The first question -- there was 14 a run-on there, but is this research article 15 advocating the benchmark dose approach? 16 A. This article is advocating a 17 very specific use of the benchmark dose 18 approach for analyzing in vitro data. 19 Q. So is this article, yes or no, 20 advocating the benchmark dose approach? 21 MS. LOCKARD: Objection, form, 22 asked and answered. 23 A. This article is using the 24 benchmark dose approach on in vitro genetic</p>	<p style="text-align: right;">Page 208</p> <p>1 pull up the next research article, 2 Permitted Daily Exposure Limits for 3 Noteworthy N-nitrosamines. 4 (Whereupon, Deposition Exhibit 5 Johnson-15, Permitted daily exposure 6 limits for noteworthy N-nitrosamines, 7 by Johnson et al, was marked for 8 identification.) 9 THE STENOGRAPHER: Exhibit 15. 10 BY MS. BOGDAN: 11 Q. Please let me know, Doctor, 12 when you can see the exhibit. 13 A. I can see the exhibit. 14 Q. And when was this research 15 article published? 16 A. It was accepted the 11th of May 17 2021. 18 Q. And in the Conflict of Interest 19 section, which is towards the back of the 20 article, three or four pages from the end... 21 A. Yes. I've got that. 22 Q. Was there a conflict of 23 interest that you noted there? 24 A. There's a conflict of interest</p>
<p style="text-align: right;">Page 207</p> <p>1 toxicology data and showing the benefits of 2 that for in vitro genetic toxicology data. 3 BY MS. BOGDAN: 4 Q. So this article is using the 5 benchmark dose approach? 6 A. This article is using the 7 benchmark dose approach on in vitro genetic 8 toxicology data. 9 Q. And in this case, in your 10 expert report, you're using the benchmark 11 dose approach, correct? 12 A. I used the benchmark dose 13 approach for the in vivo data in a different 14 manner to how we use it here for these 15 in vitro data. And in my report, where I 16 based my judgment on my cancer-derived BMD 17 using the quantum approach, using model 18 averaging of that suite of models specific 19 for cancer bioassay data analysis, which is 20 very independent and different to this 21 utility of it for in vitro genetic toxicology 22 data, there's quite a large difference in 23 those approaches. 24 MS. BOGDAN: If we could please</p>	<p style="text-align: right;">Page 209</p> <p>1 I stated in this section. 2 Q. Are you G.E.J.? 3 A. I am G.E.J. in this instance. 4 Q. And did you write that conflict 5 of interest language? 6 A. I did write this conflict of 7 interest language. 8 Q. And what did you write? 9 A. G.E.J., which is me, is a 10 consultant who evaluates the risks posed by 11 pharmaceutical impurities. His clients did 12 not influence the content of this manuscript. 13 The other authors do not declare any 14 conflicts of interest. 15 Q. And what caused you to write 16 that conflict of interest? 17 A. Because I was working on 18 nitrosamines, and I was working on 19 nitrosamines with Teva and GT, and also an 20 expanded version of this, including 21 confidence intervals around the PDE from my 22 cancer-derived BMD were part of my risk 23 assessment that were submitted for my expert 24 opinion to Teva and GT.</p>

<p style="text-align: right;">Page 210</p> <p>1 So because of that, I saw that</p> <p>2 there was some level that should be disclosed</p> <p>3 in this Conflict of Interest section.</p> <p>4 Q. Did you disclose in the</p> <p>5 Conflict of Interest section who -- what type</p> <p>6 of clients you had?</p> <p>7 A. Pharmaceutical clients.</p> <p>8 Q. I don't -- where did you write</p> <p>9 that you have pharmaceutical clients?</p> <p>10 A. G.E.J. is a consultant who</p> <p>11 evaluates the risks posed by pharmaceutical</p> <p>12 impurities. His clients did not influence --</p> <p>13 so I'm a consultant who evaluates. If I</p> <p>14 consult, then I work with the company to</p> <p>15 evaluate pharmaceutical impurities, which</p> <p>16 would be with a pharmaceutical company.</p> <p>17 Q. Couldn't you be a consultant</p> <p>18 that evaluates the risks posed to the</p> <p>19 patients on behalf of the patients?</p> <p>20 MS. LOCKARD: Objection, calls</p> <p>21 for speculation.</p> <p>22 A. I do not know.</p> <p>23 BY MS. BOGDAN:</p> <p>24 Q. Is there anything in that</p>	<p style="text-align: right;">Page 212</p> <p>1 that precedes the ones that are highlighted</p> <p>2 here.</p> <p>3 A. I'm not looking at your copy.</p> <p>4 Apologies. Okay, now I am. Can you</p> <p>5 rehighlight that section, please? Okay.</p> <p>6 And what was your question</p> <p>7 again?</p> <p>8 Q. The section or the statement</p> <p>9 that says: The other authors do not declare</p> <p>10 any conflicts of interest.</p> <p>11 Do you see that?</p> <p>12 A. I do see that.</p> <p>13 Q. Did you have any specific</p> <p>14 conversation with the other authors regarding</p> <p>15 conflicts of interest or is that something</p> <p>16 they would independently report?</p> <p>17 A. I do not know. They saw --</p> <p>18 this was part of the document that all</p> <p>19 coauthors saw. That's my level of</p> <p>20 understanding here.</p> <p>21 Q. With regard to Bhaskar</p> <p>22 Gollapudi who works for Exponent, do you know</p> <p>23 whether he had any conflicts of interest?</p> <p>24 A. I do not know.</p>
<p style="text-align: right;">Page 211</p> <p>1 Conflict of Interest section that explains</p> <p>2 that you are working for the pharmaceutical</p> <p>3 companies?</p> <p>4 A. I think it does, yes.</p> <p>5 Q. Because it says that you are a</p> <p>6 consultant who evaluates the risk posed by</p> <p>7 pharmaceutical impurities?</p> <p>8 A. That's my interpretation of</p> <p>9 that statement, yes.</p> <p>10 Q. Did you consult anyone with</p> <p>11 regard to the language that you were choosing</p> <p>12 to use in the Conflict of Interest section?</p> <p>13 A. I used this language based on</p> <p>14 the language I've seen from other</p> <p>15 pharmaceutical consultants in this area.</p> <p>16 Q. And where had you seen this</p> <p>17 language used before, in this particular</p> <p>18 journal, Environmental and Molecular</p> <p>19 Mutagenesis?</p> <p>20 A. I do not know where I found it</p> <p>21 previously, but I still think it is a good</p> <p>22 statement.</p> <p>23 Q. Now, in this conflict of</p> <p>24 interest box, it also has another sentence</p>	<p style="text-align: right;">Page 213</p> <p>1 Q. Are you familiar with Exponent?</p> <p>2 A. I'm not very familiar with</p> <p>3 Exponent, but I'm aware of some of their</p> <p>4 consultants.</p> <p>5 Q. Who are you aware of other than</p> <p>6 Bhaskar Gollapudi?</p> <p>7 A. There is two other coauthors on</p> <p>8 the ethylene oxide paper, although I can't</p> <p>9 recall their names, which also work for</p> <p>10 Exponent, for example.</p> <p>11 Q. Have you ever worked for</p> <p>12 Exponent?</p> <p>13 A. No. No.</p> <p>14 Q. As the lead author, did you</p> <p>15 have a choice as to where this manuscript was</p> <p>16 being sent to be considered for publication?</p> <p>17 A. Yes, I did have. Yes, I did.</p> <p>18 Q. And did you send it to any</p> <p>19 other journals other than the Environmental</p> <p>20 and Molecular Mutagenesis journal?</p> <p>21 A. No, I did not. In this area of</p> <p>22 applied genetic toxicology towards risk</p> <p>23 assessment, I realized this is the best</p> <p>24 journal for that particular topic.</p>

<p style="text-align: right;">Page 214</p> <p>1 Q. And how did you go about 2 selecting your coauthors for this 3 publication? 4 A. These coauthors were people who 5 contributed to a suitable extent within the 6 HESI GTTC to be rewarded or to maintain 7 coauthorship. And you'll see from the 8 Acknowledgements section at the end, there 9 was also other people that we had discussions 10 with who didn't meet that criteria but did 11 contribute along the lines of the suggested 12 text in that Acknowledgements section. 13 Q. I understand that they were 14 coauthors that -- were people who contributed 15 to a suitable extent, but how did you 16 identify them as being potential coauthors or 17 approach them to begin with? 18 A. Within the HESI GTTC group, 19 particularly on this topic, I do a large 20 amount of the work, I did a large amount of 21 the work, presented it to the HESI GTTC, and 22 requested if people wanted to become involved 23 in this research and could contribute to this 24 research. That was the main way of getting</p>	<p style="text-align: right;">Page 216</p> <p>1 how they could be compared to each other when 2 you use the BMDLs from the cancer and the 3 mutation datasets. Then in my report, which 4 is different to this, I then started applying 5 that in a risk assessment concept. 6 So the publication is not a 7 risk assessment, and the report becomes a 8 risk assessment through this extended 9 analysis and application of information 10 around the concentrations presented in that 11 report. And there is a bit of a -- there is 12 a large distinguishing factor along those 13 lines. 14 Q. But with regard to the position 15 that you're taking as to how to calculate the 16 PDEs for NDMA and NDEA, isn't that set forth 17 in this paper that was published in May of 18 2021? 19 A. The mutation data, we had a 20 conceptual total for the PDE calculation that 21 we put forward, and some discussion points 22 about how that could potentially change for a 23 real risk assessment from there onwards. 24 For the cancer-derived PDE</p>
<p style="text-align: right;">Page 215</p> <p>1 these coauthors involved. 2 Q. And were you the one that came 3 up with the idea or the topic for the 4 research article? 5 A. As stated at the beginning of 6 our conversation, I worked on this topic with 7 a couple of regulatory friends to assess 8 this. I realized it was an important topic, 9 and decided to devise a publication around 10 this topic, and then prepared this 11 publication with these coauthors, and openly 12 within the rest of the HESI GTTC, we created 13 the publication, and then we submitted it to 14 the -- the request itself from the journal 15 and had it accepted. 16 Q. Isn't this publication 17 involving exactly the type of work that you 18 were doing for Teva with regard to your 19 investigation into this case? 20 MS. LOCKARD: Objection, form, 21 misstates testimony. 22 A. I see this publication as a 23 case example, as an idea about what a -- this 24 approach could look like to derive PDEs and</p>	<p style="text-align: right;">Page 217</p> <p>1 where we did this off the BMDL lower, there's 2 an extended version of this risk assessment, 3 which I support, where you can do that 4 calculation as well as calculating a BMD 5 upper, so it wasn't complete in that respect. 6 Also, the composite uncertainty 7 factors were really for the global 8 population, but for a smaller population, you 9 can actually adjust these uncertainty 10 factors, even for the cancer bioassay data, 11 to reduce them from 500 to 50, which would 12 cause an order of magnitude increase on the 13 PDEs in my report. 14 So there's -- this was 15 more look at this, it can be done. Here's an 16 example. This is not the finished product. 17 My report is more this is how I am going to 18 use this for a real assessment of risk in 19 these patients. 20 Q. Did you submit your report in 21 this case for publishing and peer review? 22 MS. LOCKARD: Objection, 23 compound. 24 A. I submitted it to the clients,</p>

<p style="text-align: right;">Page 218</p> <p>1 as it was a client -- client-facing document. 2 BY MS. BOGDAN: 3 Q. Did you submit your report in 4 this case to a journal and ask that it be 5 reviewed for publication? 6 MS. LOCKARD: Objection, form, 7 compound. 8 A. I did not submit my 9 confidential report for my clients to a 10 journal. 11 BY MS. BOGDAN: 12 Q. Don't you cite in your report 13 as authority your article that was published 14 May 11th of 2021? 15 A. I cite my article, but I 16 wouldn't use the term "as authority." I cite 17 my article as the first approach of deriving 18 PDEs using basic composite uncertainty 19 factors using just the lower bound. 20 So, no, it wouldn't be as 21 what's said in the paper is absolute. It's 22 using the concepts from that and developing a 23 more extended risk assessment in my report. 24 Q. Now, with your coauthors on</p>	<p style="text-align: right;">Page 220</p> <p>1 acceptable intake based on the linear 2 extrapolation, yes. 3 Q. And similarly with regard to 4 the value that you have calculated for NDEA, 5 is that permissible daily exposure for NDEA 6 that you set forth in your publication higher 7 than the acceptable intake that has been put 8 forth by the FDA for NDEA? 9 A. That is correct. Theirs is 10 based on linear back-extrapolation. 11 Q. And would the drug companies 12 benefit from higher permissible levels of 13 NDMA and NDEA allowed in pharmaceuticals? 14 MS. LOCKARD: Objection, form, 15 speculation. 16 A. I do not know. 17 BY MS. BOGDAN: 18 Q. With higher limits of NDMA that 19 are allowed, couldn't they sell 20 pharmaceuticals that would have more NDMA in 21 them -- in them? 22 MS. LOCKARD: Objection, form, 23 speculation. 24 A. That could be one</p>
<p style="text-align: right;">Page 219</p> <p>1 this publication, you have Anthony Lynch, Jim 2 Harvey and Julia Kenny, who all work for 3 GlaxoSmithKline, correct? 4 A. That's correct. 5 Q. And GlaxoSmithKline produced 6 Zantac from 1983 to 2017; isn't that correct? 7 MS. LOCKARD: Objection, form, 8 speculation. 9 A. I do not know. 10 BY MS. BOGDAN: 11 Q. Do you know that 12 GlaxoSmithKline manufactured Zantac? 13 A. I haven't looked into that. 14 Q. Are you aware that Zantac was 15 recalled because of an issue with NDMA 16 contamination? 17 A. I was aware that there was many 18 pharmaceuticals that were recalled. 19 Q. And your conclusion that you're 20 reaching in this 2021 publication with the 21 PDE for NDMA, is that PDE higher than the 22 acceptable intake limit that's been 23 established by the FDA for NDMA? 24 A. It is higher than the</p>	<p style="text-align: right;">Page 221</p> <p>1 interpretation. 2 BY MS. BOGDAN: 3 Q. And similarly, with a raised 4 allowed limit for NDEA, wouldn't that permit 5 pharmaceutical companies to sell medicines 6 with more NDEA in it? 7 MS. LOCKARD: Objection, form, 8 speculation. 9 A. If the firm -- if the human 10 exposure limit was higher, then a higher 11 level of that substance would be shown not to 12 increase human risk at those concentrations. 13 BY MS. BOGDAN: 14 Q. All right. So we went over the 15 three authors, Lynch, Harvey and Kenny that 16 work for GSK. You have other coauthors of 17 Dobo and Kenyon, correct? 18 A. That is correct. 19 Q. And they both work for Pfizer; 20 isn't that correct? 21 A. That is correct. 22 Q. And Pfizer manufactures 23 Chantix, which was recalled this past summer 24 due to an N-nitroso contamination.</p>

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<p>1 Are you aware of that?</p> <p>2 A. I was not aware of that, and</p> <p>3 it's not articulated in this publication.</p> <p>4 Q. And Pfizer also produced</p> <p>5 Zantac. Did you know that?</p> <p>6 A. I did not know that.</p> <p>7 Q. And Zantac has also been</p> <p>8 recalled because of an N-nitrosamine</p> <p>9 contamination issue.</p> <p>10 Are you aware of that?</p> <p>11 A. I'm aware that this issue has</p> <p>12 affected many companies and many drugs have</p> <p>13 been taken from the market.</p> <p>14 Q. Now, more of your coauthors</p> <p>15 also work for pharma. You have Thybaud who</p> <p>16 works for Sanofi. Isn't that correct?</p> <p>17 A. At the time she worked for</p> <p>18 Sanofi, and now she is retired.</p> <p>19 Q. And Sanofi was another company</p> <p>20 that manufactured Zantac, which has been</p> <p>21 recalled because of NDMA contamination; isn't</p> <p>22 that correct?</p> <p>23 A. I did not know that</p> <p>24 specifically. I did not know that</p>	<p>1 of which that we've already gone through,</p> <p>2 have dealt with -- if I can find them here --</p> <p>3 benchmark dose -- let me find them here. I</p> <p>4 just put them down here -- mutations,</p> <p>5 regulatory decision-makings. There was an</p> <p>6 author by the name of Paul White. And so --</p> <p>7 A. Yeah, I've met him.</p> <p>8 Q. Yes? Right? Yes?</p> <p>9 A. Sorry, I spoke over you. Can</p> <p>10 you repeat the question? I spoke over you.</p> <p>11 Q. That's okay.</p> <p>12 Paul White was a coauthor with</p> <p>13 you on several of these earlier environmental</p> <p>14 and molecular mutagenesis publications,</p> <p>15 correct?</p> <p>16 A. Correct. That is correct.</p> <p>17 Q. Did you ask if he would be</p> <p>18 willing to coauthor the permitted daily</p> <p>19 exposure limits for the nitrosamine</p> <p>20 publication?</p> <p>21 A. I asked for his contributions,</p> <p>22 and due to workload, he was unable to commit</p> <p>23 to coauthorship. You'll see from</p> <p>24 Acknowledgements that we acknowledged the</p>
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<p>1 specifically.</p> <p>2 Q. And Sanofi has also</p> <p>3 manufactured irbesartan, which has been</p> <p>4 recalled because of NDMA and NDEA. Are you</p> <p>5 aware of that?</p> <p>6 A. I was not aware of that, but</p> <p>7 realize that many companies, including the</p> <p>8 ones listed here, would have had similar</p> <p>9 issues.</p> <p>10 Q. So except for Gollapudi, who</p> <p>11 works for Exponent, each of the other</p> <p>12 coauthors works for pharma, correct?</p> <p>13 A. And Ryan Wheeldon with Swansea</p> <p>14 University, correct, with the pharmaceutical</p> <p>15 statement.</p> <p>16 Q. And GSK, Pfizer -- I say</p> <p>17 "Sanofi," you say "Sanofi" -- they've all had</p> <p>18 issues with contamination of N-nitrosamines</p> <p>19 in their drugs?</p> <p>20 MS. LOCKARD: Objection.</p> <p>21 That's not a question. Calls for</p> <p>22 speculation if it is.</p> <p>23 BY MS. BOGDAN:</p> <p>24 Q. On previous publications, some</p>	<p>1 discussions with Paul White in that section.</p> <p>2 At this time, he was not a</p> <p>3 cochair of this HESI GTTC quantitative group</p> <p>4 with me. It was myself and Andreas.</p> <p>5 Q. And when you say you asked for</p> <p>6 his contributions, meaning you asked him to</p> <p>7 be a coauthor?</p> <p>8 A. Meaning we had discussions</p> <p>9 around the work. We had just written a paper</p> <p>10 on uncertainty factors that could be applied</p> <p>11 to the genetic toxicity PDE. Those</p> <p>12 discussions were useful. Those sorts of</p> <p>13 discussions.</p> <p>14 Q. Other than work, did he give</p> <p>15 any other reason that he was unable to commit</p> <p>16 to being a coauthor?</p> <p>17 A. No, that would be workload</p> <p>18 issues for Paul White.</p> <p>19 MS. LOCKARD: Do you need</p> <p>20 something to drink?</p> <p>21 THE WITNESS: Yeah, is there</p> <p>22 any more Coke or is that all</p> <p>23 downstairs?</p> <p>24 (Comments off the stenographic</p>

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1 record.)
2 BY MS. BOGDAN:
3 Q. When was it when you were asked
4 to not only serve as an expert for Teva but
5 then to serve as an expert for all defendants
6 in the case?
7 MS. LOCKARD: Objection, asked
8 and answered.
9 A. As a response, we can see from
10 the invoices it was when I changed from
11 consultancy to reporting, when I was
12 generating the report. I was made aware at
13 that time that it was for the other clients,
14 extended from Teva. That was beginning of
15 2021.
16 BY MS. BOGDAN:
17 Q. Is there something on the
18 invoice that indicates to you that that is
19 the timing of when that took place?
20 A. Yes. So in my 05-07-2021
21 invoice for 35 hours, the discussions around
22 reporting moved me really from understanding
23 the whole area as a whole and having
24 discussions with Teva and GT to focusing on a

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1 report for the client and the extended board
2 of clients.
3 MS. BOGDAN: Could we pull up
4 the retainer letter, please, between
5 Greenberg Traurig and Dr. Johnson.
6 (Whereupon, Deposition Exhibit
7 Johnson-16, 6/8/21 Greenberg Traurig
8 Letter, was marked for
9 identification.)
10 THE STENOGRAPHER: Exhibit 16.
11 BY MS. BOGDAN:
12 Q. Doctor, do you want to let me
13 know when you see that?
14 A. I see that.
15 Q. Oh, okay. I was just waiting.
16 I didn't know if it was taking time for it to
17 load, so...
18 Do you recognize that
19 correspondence?
20 A. I do recognize that
21 correspondence.
22 Q. And when did you receive this
23 correspondence relevant to when you were
24 asked to be an expert on behalf of all

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1 defendants?
2 A. I do not know.
3 Q. Was it after you were asked to
4 be an expert on behalf of all defendants?
5 MS. LOCKARD: Objection, form,
6 asked and answered.
7 THE WITNESS: Yes.
8 A. I do not know.
9 BY MS. BOGDAN:
10 Q. Referring you to the first
11 paragraph of the letter, it says a couple of
12 sentences down: This letter will confirm our
13 agreement to retain you as a(n)
14 consultant/expert in connection with the
15 above-styled litigation on behalf of Teva.
16 Do you see that sentence?
17 A. I see that sentence.
18 Q. Did you receive any type of
19 similar letter from Greenberg Traurig after
20 you were asked to serve as an expert on
21 behalf of all defendants?
22 MS. LOCKARD: Objection, form.
23 It's confusing.
24 A. I do not know. Contracts are

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1 done through Swansea Innovations.
2 BY MS. BOGDAN:
3 Q. When you say contracts are done
4 through Swansea Innovations, is there a
5 separate writing that Swansea Innovations has
6 with clients in order to hire you as a
7 consultant or expert?
8 A. Could you say that again,
9 please.
10 Q. You answered the last question
11 where you said: I know contracts are done
12 through Swansea Innovations.
13 So is there a separate writing
14 that Swansea Innovations has that would
15 pertain to your work as a consultant, slash,
16 expert for Teva?
17 A. I understand now.
18 They do not. They would have
19 this. That's my understanding.
20 Q. Now, in this letter it
21 indicates on the second page that materials
22 for your initial review would be sent to you
23 separately via secure FTP, which is the first
24 sentence on the second page.

<p style="text-align: right;">Page 230</p> <p>1 Were materials sent to you to 2 review? 3 A. This -- I think they refer to a 4 list of materials that were sent to me, and 5 yes, they were sent to me. 6 Q. And are those included in your 7 list of materials considered? 8 A. Yes. 9 Q. And then down further on that 10 page, there's a paragraph that starts "Please 11 note." Can you read that sentence, please. 12 A. Please note we are not asking 13 for any sort of written report or written 14 work product at this time. Once you have 15 completed your review of the initial 16 materials, please call me to arrange a 17 convenient time when you can discuss your 18 opinions on the case. 19 Q. And did you follow that 20 instruction? 21 A. I was compiling a report was my 22 understanding. 23 Q. And when did you start to 24 compile the report?</p>	<p style="text-align: right;">Page 232</p> <p>1 article entitled Permitted Daily Exposure 2 Limits for Noteworthy Nitrosamines, who 3 funded the work for that study? 4 A. It was done independently of 5 research funding. It was using published 6 data that we reanalyzed and put forward, but 7 due to my work with GT and Teva at that time, 8 I acknowledged in the Conflict of Interest 9 section that statement. 10 MS. BOGDAN: If we could please 11 pull that exhibit up. It's the 12 research article entitled Permitted. 13 And what exhibit number has 14 this been marked? 15 TRIAL TECHNICIAN: This is, I 16 believe, 14 of our number, so it was 17 marked as Exhibit 15. 18 BY MS. BOGDAN: 19 Q. Directing your attention to the 20 first page where it says Funding Information 21 on the left-hand side? 22 A. Okay. Yes, I can see that. 23 Q. What does it say there? 24 A. Baxter International Inc.</p>
<p style="text-align: right;">Page 231</p> <p>1 A. I don't know precisely the 2 answer to that. 3 Q. Can you provide an estimate 4 with regard to when you started the report 5 relative to when you finished it? 6 A. I cannot. 7 Q. You cannot state how many 8 months you were working on the report? 9 A. Not precisely. 10 THE WITNESS: May I ask for a 11 break to get another bottle of Diet 12 Coke? 13 MS. LOCKARD: Is this a good 14 time, Rosemarie? 15 MS. BOGDAN: Sure. We can take 16 a five-minute break. 17 THE VIDEOGRAPHER: Going off 18 the record. The time is 3:20 p.m. 19 (Recess taken, 3:20 p.m. to 20 3:34 p.m. BST) 21 THE VIDEOGRAPHER: Back on the 22 record. The time is 3:34 p.m. 23 BY MS. BOGDAN: 24 Q. With regard to the research</p>	<p style="text-align: right;">Page 233</p> <p>1 Q. And what type of company is 2 Baxter? 3 MS. LOCKARD: Objection, form, 4 ambiguous. 5 A. From my understanding, it is a 6 medicinal product company. 7 BY MS. BOGDAN: 8 Q. As the lead author, did you go 9 about acquiring the funding for this research 10 article? 11 MS. LOCKARD: Objection, vague. 12 A. This Baxter International 13 Incorporated funding was used by Ryan 14 Wheeldon to pay for his tuition fees during 15 his Ph.D. 16 BY MS. BOGDAN: 17 Q. So it was his tuition fees and 18 then he spent his time contributing to this 19 paper, and that's what that funding 20 information indicates? 21 A. That's the entirety of that. 22 That's what that funding indicates. 23 Q. Who paid you for your time in 24 writing and authoring this research article?</p>

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1 A. This was something I did off my
2 own back in my own time with the HESI GTTC.
3 I contribute my time without receiving
4 additional funding because this is my
5 research interest.
6 This particular topic I've been
7 working on my whole academic life, and I put
8 in a lot of time on that basis without
9 receiving funding.
10 But I'll state it again.
11 Because of the interest and link to my
12 clients, Teva and GT, I acknowledged that
13 there was that conflict of interest there.
14 So no funding from other sources. I hope
15 that statement was clear.
16 Q. Did you use any of the
17 knowledge you had gained doing your
18 consulting work on this litigation regarding
19 nitrosamine contamination in valsartan drugs
20 when writing this research article?
21 MS. LOCKARD: Objection, form,
22 vague.
23 A. I did not. From day one when I
24 was made aware of this issue of the

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1 substance or these substances that were
2 carrying out adducts and mutations through
3 the mechanism that I understood entirely, I
4 had the knowledge at hand to be able to write
5 this pretty much from day one.
6 BY MS. BOGDAN:
7 Q. When did you begin working on
8 this research article?
9 A. The concepts contained within
10 the research article would date back to that
11 Informa Impurities conference where I put
12 forward the concept of it and then refined
13 that and my understanding of it throughout,
14 and then preparation of the manuscript. PI
15 cannot give you dates and times, but it was
16 in a -- I worked on it when I could and
17 prepared it and submitted it as you've seen.
18 Q. Did you start work on this
19 before you were retained to be a consultant
20 for Teva in this litigation?
21 A. As stated, I worked on this
22 concept and did a lot of analysis before
23 that, correct.
24 Q. When did the first draft of

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1 this research article come into being?
2 A. I do not know.
3 Q. Was it in 2018?
4 A. I don't think I'm that
5 efficient. I don't think so.
6 Q. Was it in 2019?
7 A. I do not know.
8 Q. Did this go out for peer
9 review?
10 A. It did go out for peer review.
11 Q. Did it get any critical
12 comments as part of the peer-review process?
13 A. It got some detailed
14 peer-reviewed comments, some critical, which
15 we addressed and overcame and changed
16 accordingly. Some supportive. Same from the
17 editor as well. We addressed the comments,
18 and they were happy, we were happy. The
19 editor who works at Health Canada supported
20 that those changes were accepted, and the
21 peer-review process was adhered to, and the
22 editorial process as well.
23 Q. And what were the changes that
24 were made in response to the critical

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1 peer-review comments?
2 A. I do not know.
3 Q. Do you remember the topic areas
4 of the critical peer-review comments?
5 A. I do not. Mostly stylistic,
6 around wording, I think.
7 Q. How many research articles have
8 you authored with a coauthor affiliated with
9 Exponent?
10 A. I do not know.
11 Q. Would you say there's been more
12 than five?
13 A. I do not know.
14 MS. BOGDAN: Could we please
15 pull up exhibit Business Ethics
16 Magazine by FairWarning.org.
17 (Whereupon, Deposition Exhibit
18 Johnson-17, Business Ethics Article,
19 Legal Scrapes Turn to Science-for-Hire
20 Giant Exponent, was marked for
21 identification.)
22 THE STENOGRAPHER: Exhibit 17.
23 THE WITNESS: Not yet.
24 TRIAL TECHNICIAN: Give me one

<p>Page 238</p> <p>1 moment. It's giving me some trouble. 2 Hang on. 3 There we go, should see it now. 4 THE WITNESS: I can see it now, 5 Exhibit 17 is loading. It's on my 6 screen. 7 BY MS. BOGDAN: 8 Q. Are you aware of articles like 9 this criticizing Exponent and the work that 10 it does on behalf of industry? 11 A. I'm not aware of this article 12 or similar ones. 13 Q. Directing your attention to the 14 last statement on the first page, which 15 reads: It's a go-to destination for major 16 industries with liability problems, even as 17 it is derided by critics as hired -- as a 18 hired gun whose findings are for sale. 19 Do you see that? 20 A. I see that. 21 Q. Are you aware of allegations 22 like that regarding Exponent? 23 A. No, I'm not. 24 Q. If we could turn to page 3 --</p> <p>Page 239</p> <p>1 or actually, page 2 of the document. 2 Directing your attention to the last 3 paragraph. 4 A. I can see it. 5 Q. Okay. Where it reads: 6 Opponents say Exponent's scientists and 7 engineers routinely bend conclusions to the 8 needs of clients, noting that the company in 9 the 1990s supported the tobacco industry in 10 denying the lung cancer risk of secondhand 11 smoke. 12 Were you aware of that 13 allegation? 14 MS. LOCKARD: Objection, vague. 15 A. I'm not aware of that statement 16 from the 1990s. 17 BY MS. BOGDAN: 18 Q. And with regard to the second 19 statement: The firm's forte, they say, is 20 doubt science, muddying the waters by 21 attacking research showing evidence of harm, 22 highlighting or exaggerating scientific 23 uncertainties about health hazards, and 24 calling for more research to delay action.</p>	<p>Page 240</p> <p>1 The result, critics say, is a pro-industry 2 imprint on scientific literature. 3 Are you aware of those types of 4 allegations against Exponent? 5 A. I'm not aware of those types of 6 allegations towards Exponent. 7 Q. And if I could direct you to 8 page 5, this is the middle paragraph. 9 A. I think I can see it, next to a 10 picture of someone; is that correct? 11 Q. That's a picture of Roger L. 12 McCarthy, a former CEO and chairman of 13 Exponent. 14 A. I see that. 15 Q. What it says is: The drive for 16 repeat business is not the only reason. 17 Clients who fund research often own the data 18 that is generated and must approve the 19 publication of results, said Roger L. 20 McCarthy, a former Exponent CEO and chairman, 21 who retired from the company in 2009 and 22 agreed to speak with FairWarning. 23 Are you aware of those 24 statements of the former CEO of the company?</p> <p>Page 241</p> <p>1 A. This is the first time I have 2 seen that statement. 3 Q. We can take that down. 4 Would it be fair to say that 5 you've authored more than five articles with 6 Exponent coauthors? 7 MS. LOCKARD: Objection, asked 8 and answered. 9 A. I do not know. 10 BY MS. BOGDAN: 11 Q. Well, how many articles have 12 you authored with Gollapudi? 13 A. I do not know, but if you would 14 wish me to count them, that could be another 15 question. 16 Q. Not here. 17 We have the Permitted Daily 18 Exposure Limits For Noteworthy Nitrosamines, 19 that was with Gollapudi, right? 20 A. Yes. Can you give me the dates 21 when we're going through these, please? 22 Q. Sure. That was accepted 23 May 11th of 2021. 24 A. Excellent. I agree that is one</p>
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1 with Bhaskar Gollapudi.
 2 Q. Genotoxicity as a
 3 Toxicologically Relevant Endpoint to Inform
 4 Risk Assessment: A case study with ethyl
 5 oxide. That was September 4th of 2020. That
 6 was with Gollapudi, correct?
 7 A. That is correct.
 8 Q. Here's one from 2016,
 9 Next-Generation Testing Strategy for
 10 Assessment of Genomic Damage: A conceptual
 11 framework -- (audio malfunction) --
 12 (Clarification requested by the
 13 stenographer.)
 14 BY MS. BOGDAN:
 15 Q. -- and considerations.
 16 A. The first author of that one,
 17 please?
 18 Q. Dearfield, Kerry Dearfield.
 19 A. Yeah, that's correct. He's
 20 ex-EPA and USDA, thank you.
 21 Q. Here is one from 2014,
 22 Derivation of Point of Departure Estimates in
 23 Genetic Toxicology Studies?
 24 A. Yeah, that was me, first

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1 author.
 2 Q. Here's another one, Mutation as
 3 a Toxicological Endpoint for Regulatory
 4 Decision-Making. That was published online,
 5 October 10th of 2019?
 6 A. Yeah, with Bob Heflich from FDA
 7 as first author. I see that, yes.
 8 Q. Yeah. All right. And those
 9 are the ones I have.
 10 A. Okay.
 11 MS. BOGDAN: If we could put up
 12 the article entitled Tolerability of
 13 Risk: A commentary on the nitrosamine
 14 contamination issue.
 15 (Whereupon, Deposition Exhibit
 16 Johnson-18, Tolerability of risk: A
 17 commentary on the nitrosamine
 18 contamination issue, by Elder et al,
 19 was marked for identification.)
 20 BY MS. BOGDAN:
 21 Q. Are you a coauthor of that
 22 study?
 23 THE WITNESS: Yeah, it's not
 24 appearing as an exhibit yet. Is that

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1 Exhibit 18?
 2 MS. BOGDAN: This is going to
 3 be marked a new exhibit. I don't
 4 think it's been marked yet.
 5 THE WITNESS: Okay. I can see
 6 it, thank you.
 7 MS. BOGDAN: And it has been
 8 marked as Exhibit 18 for
 9 identification?
 10 THE STENOGRAPHER: Yes.
 11 BY MS. BOGDAN:
 12 Q. Are you a coauthor of that
 13 study?
 14 A. I'm a coauthor of this
 15 commentary, yes.
 16 Q. And did you disclose a conflict
 17 of interest in this commentary that was
 18 published in the Journal of Pharmaceutical
 19 Sciences?
 20 A. We did not, no.
 21 Q. And this commentary is about
 22 the nitrosamine contamination issue in
 23 pharmaceuticals, correct?
 24 A. It is a commentary on the

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1 nitrosamine contamination issue, correct.
 2 MS. BOGDAN: If we could please
 3 pull up the Journal of Pharmaceutical
 4 Sciences introduction, types of
 5 articles and declaration of interest
 6 exhibit, please.
 7 (Whereupon, Deposition Exhibit
 8 Johnson-19, JPharmSci Declaration of
 9 Interest Policy, was marked for
 10 identification.)
 11 THE STENOGRAPHER: Exhibit 19.
 12 BY MS. BOGDAN:
 13 Q. And if you could please go to
 14 page 4 of that exhibit.
 15 A. Okay. Page 4.
 16 Q. And under Declaration of
 17 Interest --
 18 A. I can see that.
 19 Q. -- it says: All authors must
 20 disclose any financial and personal
 21 relationships with other people or
 22 organizations that could inappropriately
 23 influence, bias, their work. Examples of
 24 potential competing interests include

<p>Page 246</p> <p>1 employment, consultancies, stock ownership, 2 honoraria, paid expert testimony, patent 3 applications/registrations, and grants or 4 other funding. 5 Do you see that? 6 A. Yes, I see that. 7 Q. And authors must disclose any 8 interest in two places: A summary 9 declaration of interest statement in the 10 title page file, or the manuscript file. If 11 there are no interests to declare, then 12 please state this: Declarations of interest, 13 none. 14 Do you see that? 15 A. I do see that. 16 Q. This is the declaration of 17 interest for the Journal of Pharmaceutical 18 Sciences where you published general 19 commentary entitled Tolerability of Risk: A 20 commentary on the nitrosamine contamination 21 issue, is it not? 22 A. That is the journal associated 23 with that publication, yes. 24 MS. BOGDAN: We can take that</p> <p>Page 247</p> <p>1 exhibit down, please. Thank you. 2 I'm trying to get my spot here. 3 Okay. If we could please pull up the 4 FDA Laboratory analysis of valsartan 5 products. 6 (Whereupon, Deposition Exhibit 7 Johnson-20, Laboratory Analysis of 8 Valsartan Products, was marked for 9 identification.) 10 THE STENOGRAPHER: Exhibit 19. 11 TRIAL TECHNICIAN: That's 12 Exhibit 20, Mike. 13 BY MS. BOGDAN: 14 Q. Let me know, Doctor, once it's 15 up on your screen. 16 A. It's just come up on my screen. 17 Q. Do you recognize that document? 18 A. I recognize the table and this 19 document, yes. 20 Q. What do you recognize that to 21 be? 22 A. I recognize this to be the FDA 23 analysis as stated in the text of these 24 substances in the finished product, drugs and</p>	<p>Page 248</p> <p>1 APIs. 2 Q. All right. Let's -- do you 3 have a hard copy in front of you so you can 4 see the second and third page? 5 A. I have a hard copy in front of 6 me. I didn't catch the second statement. 7 MS. LOCKARD: He has a hard 8 copy. Let me just make sure it's the 9 same thing you have. 10 MS. BOGDAN: If you could just 11 move this to the second and third page 12 so that the witness can see the whole 13 exhibit. 14 MS. LOCKARD: Yes, it appears 15 to be the same as your exhibit. 16 BY MS. BOGDAN: 17 Q. Did you review this document as 18 part of your investigation into this matter? 19 A. I reviewed it and included the 20 metrics in my report. 21 Q. Now, when you say you included 22 the metrics, what are you referring to? 23 A. Oh, I included the table, 24 including the numbers and details into my</p> <p>Page 249</p> <p>1 report, as far as I'm aware. 2 Q. What information does the table 3 have in it? 4 A. It has a row of columns. We've 5 got Company, Product Name, Lots Tested, NDMA 6 levels and NDEA levels within those lots 7 tested from the different companies in a 8 different size and different tablets. 9 Q. And did you put this 10 information directly into your report? 11 A. I put this directly into my 12 report. I also included an additional 13 modification of the midpoint based on these 14 numbers, where appropriate. 15 Q. And when you say you added the 16 midpoint, why did you do that? 17 A. I do a lot of statistical 18 analysis, and I like to have as much 19 information for metrics as possible. The 20 numbers were not available to carry out means 21 and standard deviations, and the midpoints 22 are calculated as another useful metric for 23 me to use in my analyses. 24 Q. So you did the midpoint of the</p>
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1 lots that were tested as shown in the table?
2 A. Yes.
3 Q. And how many lots approximately
4 were tested for each of the manufacturers'
5 products?
6 A. They vary. The lots that were
7 tested according to this table, average --
8 there was lots of three lots tested for
9 certain companies. There's some where six
10 lots were tested. There's variation in the
11 number of lots tested.
12 Q. Do you know how many lots of --
13 for example, let's take Aurobindo at the top.
14 Do you see that at the very
15 top?
16 A. I see that at the very top.
17 Q. And you see amlodipine,
18 10 milligrams/valsartan -- valsartan,
19 320 milligrams?
20 A. Yes, I do see that.
21 Q. Okay. Do you know how many
22 lots Aurobindo actually made of that
23 medication during the relevant time period
24 when the contamination took place?

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1 A. I do not know that number.
2 Q. Did you make inquiry to find
3 out the number of lots that were
4 manufactured?
5 A. I did not inquire to that, but
6 the available data from these companies on
7 the lots tested was made available to me, but
8 I did not request the number that you've just
9 suggested.
10 Q. So you didn't request for any
11 of the companies that are listed in this
12 exhibit information about the total number of
13 lots they actually manufactured of each of
14 these products?
15 A. No. My acceptance that the FDA
16 is a regulatory body that did this analysis
17 and presented a useful body of information
18 was enough for me to present this table as it
19 was.
20 Q. Well, you testified that you
21 like to have as much information for metrics
22 as possible; is that true?
23 A. Where suitable, lots of metrics
24 can be very useful, and access to that

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1 information can be useful.
2 Q. Did you ask for the information
3 regarding the test results that the
4 individual manufacturers had for the NDMA and
5 NDEA levels in their product based on the
6 testing they had performed?
7 A. Yes, and I was provided with
8 that information, had access to that
9 information, and saw that there was no real
10 issue in going with these numbers that I
11 presented here from FDA to the final product.
12 Q. Did you create any type of
13 writing or chart comparing the values that
14 you looked at for the defendants' internal
15 testing results with the results that are
16 reported --
17 A. I did not.
18 Q. -- on this exhibit?
19 A. I did not. Apologies for
20 speaking over you.
21 Q. No, that's -- we have a little
22 bit of a delay going on. It seems to have
23 gotten a little worse, so I'll try to make
24 sure I have a real pause before I start

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1 speaking again.
2 If you reviewed the internal
3 test results from the manufacturer's testing
4 of their product, then wouldn't you have had
5 information regarding the lots that were
6 manufactured?
7 A. That information -- I was --
8 the interest from those lots from my
9 perspective was upper limits and whether they
10 exceeded the upper limits in this final
11 product presented in the FDA table. And from
12 my discussions and observations from that
13 information, I was happy to go with this FDA
14 table.
15 Q. And did you systematically go
16 through each of the manufacturers listed on
17 the left to see if their internal test
18 results showed levels that were higher than
19 what was reported by the FDA on this table?
20 MS. LOCKARD: Objection, form,
21 ambiguous.
22 A. I had this information to hand.
23 It was available for my consideration, and I
24 did consider that those -- those data from

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1 the different companies.
2 BY MS. BOGDAN:
3 Q. And how many internal test
4 result documents did you review?
5 A. I do not know.
6 Q. Did you review hundreds of
7 internal test results from the company
8 showing the levels of NDMA and NDEA in their
9 products?
10 A. I do not know.
11 Q. Can you point me to where on
12 your list of materials considered internal
13 testing data is for the companies? Do you
14 have a --
15 MS. LOCKARD: I'm turning to
16 the corporate document section, and
17 I'm not pointing anything out.
18 BY MS. BOGDAN:
19 Q. Doctor, did you make any note
20 on your list of materials considered which of
21 those corporate documents you're referring to
22 having reviewed with regard to the internal
23 testing data from the companies?
24 A. I --

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1 MS. LOCKARD: You can take time
2 to look through that.
3 THE WITNESS: Okay.
4 MS. LOCKARD: I just put it in
5 front of you.
6 (Document review.)
7 A. I think it comes under the
8 testing results, to -- say, Mylan API testing
9 results on, say, page 19. Maybe other
10 documents with similar titles as well. As
11 I've suggested, I've not made notes as to
12 which of these documents I've reviewed. I
13 reviewed them as and when they were provided
14 by me -- provided to me.
15 BY MS. BOGDAN:
16 Q. Did you make any efforts to
17 take the midpoint for the internal test
18 results that the companies arrived at when
19 doing NDMA and NDEA testing of their
20 products?
21 A. I did not with those. My
22 interest was in upper limits from those
23 documents.
24 Q. If your interest was in upper

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1 limits, why did you calculate the midpoint?
2 A. For additional information from
3 the FDA analyses.
4 Q. When calculating something like
5 the midpoint of testing values -- strike
6 that.
7 How did you make a
8 determination that the test results that the
9 FDA reported were representative of all of
10 the product that each of the defendants had
11 manufactured over the time period the
12 contamination took place?
13 A. I made the determination that
14 the FDA was the regulatory body in charge of
15 risk assessment for these batches within the
16 U.S., and that this was a suitable data
17 source.
18 Q. And this data source reports
19 the test results on between one and six
20 batches of product per type, per
21 manufacturer, correct?
22 A. That is correct. And it was
23 analyzed in a consistent manner by the same
24 people to enable these comparisons as well.

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1 Q. However, if there were hundreds
2 of batches and lots that were made, wouldn't
3 it be better to have information regarding
4 all of the test results as opposed to one,
5 two, three, four, five or six for a
6 particular batch?
7 A. In science and risk assessment,
8 decisions have to be made at a point to make
9 a decision on a certain dataset. You don't
10 need infinite data sources unless you're
11 aware of something that extremely deviates
12 from the data presented here. And to my
13 knowledge to date, that has not been
14 presented, and these are robust to allow us
15 to make this decision.
16 Q. You used the word "robust."
17 What makes these results robust if the lots
18 tested were either one, two, three, four,
19 five or six lots in comparison to hundreds
20 that were made?
21 A. My term of "robust" would be
22 from -- analyzed by the FDA using extremely
23 top-end machinery to get very precise results
24 in a way that they're happy to carry out a

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1 risk assessment on. I would use here -- that
2 was expansion on my use of the term "robust."
3 Q. You're appearing as an expert
4 on behalf of the defendants in this
5 litigation, correct?
6 A. Yes, that is correct.
7 Q. Do you have any reason as you
8 sit there to believe that their own testing
9 of the product that they manufactured results
10 were incorrect or wrong?
11 A. I do not have any reason to
12 make that assumption, and I'm not an expert
13 in testing samples such as these using
14 techniques such as mass spectrometry.
15 Q. Through your investigation into
16 this matter, did you learn any information
17 that would lead you to believe that the
18 defendant's own testing of its product for
19 NDMA or NDEA was flawed?
20 A. I did. I looked at the
21 information, had discussions, and found no
22 evidence that the analyses were flawed.
23 Q. Did you request test results
24 from either ZHP, Princeton or Solco regarding

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1 the product that they manufactured?
2 A. I'm quite confident that I've
3 got that information -- I've had that
4 information passed to me and highlighted as
5 being the information from those companies
6 throughout this time.
7 Q. And did you record that
8 information in your report?
9 A. The information that I have
10 accessed and have considered, these would be
11 in the list of materials provided or whatever
12 term we have for that long list.
13 Q. And that list is completely
14 comprehensive of what you reviewed, correct?
15 A. As far as I'm aware, that is
16 correct.
17 MS. BOGDAN: If we could please
18 pull up the exhibit which is the
19 general advice letter of the FDA.
20 (Whereupon, Deposition Exhibit
21 Johnson-21, USFDA General Advice
22 Letter, was marked for
23 identification.)
24 THE STENOGRAPHER: Exhibit 21.

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1 MS. LOCKARD: What number
2 exhibit would this be?
3 MS. BOGDAN: 21, I believe.
4 THE WITNESS: After this set of
5 questions, can I request another short
6 break? Getting -- another short
7 break, please.
8 MS. BOGDAN: Why don't we
9 actually, if you would like a break,
10 take one before we start asking
11 questions about this document. I'd
12 rather not break while I'm working
13 with the document. So does that work
14 for you?
15 THE WITNESS: Works for me.
16 THE VIDEOGRAPHER: Going off
17 the record. The time is 4:17 p.m.
18 (Recess taken, 4:17 p.m. to
19 4:32 p.m. BST)
20 THE VIDEOGRAPHER: We're back
21 on the record. The time is 4:32 p.m.
22 BY MS. BOGDAN:
23 Q. Dr. Johnson, is this exhibit,
24 which is the general advice letter from the

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1 FDA, now up on the screen?
2 A. Yes, it is. Could you make it
3 larger -- or I could open it -- I could open
4 it in exhibits.
5 Q. I think it was just made
6 larger. Can you see it now?
7 A. I can see it now, that's great.
8 Q. Yeah. Did you review this
9 letter as part of your investigation into
10 this matter?
11 A. I can't recall this specific
12 letter.
13 Q. All right. Well, this letter
14 in the first sentence, do you see it's
15 referring to angiotensin II receptor
16 blockers, ARB?
17 A. Yes. Yes, I can see that.
18 Q. Is valsartan an ARB?
19 A. To my understanding, it is.
20 Q. If we could go down to the
21 third paragraph, could you read the first
22 sentence in the third paragraph?
23 A. Tell me the first word of that
24 sentence, please.

<p style="text-align: right;">Page 262</p> <p>1 Q. "Nitrosamine." 2 A. Okay. Reading this out: 3 Nitrosamine compounds are potent genotoxic 4 carcinogens in several nonclinical species 5 and are classified as probable human 6 carcinogens by the International Agency for 7 Research on Cancer, brackets, IARC. 8 Q. Do you agree with that 9 statement? 10 A. I agree that IARC classify 11 nitrosamine compounds as potent genotoxic 12 carcinogens in many instances, and that they 13 are probable human carcinogens. 14 Q. Are NDMA and NDEA nitrosamine 15 compounds? 16 A. Yes, they are nitrosamine 17 compounds, NDMA and NDEA. 18 Q. Do you agree that NDMA is a 19 potent genotoxic carcinogen? 20 A. The term "potency," from this 21 definition -- it's taken from the TD linear 22 back-extrapolation for potency. So I agree 23 that they are genotoxic carcinogens, but the 24 definition they use for "potent" relies on</p>	<p style="text-align: right;">Page 264</p> <p>1 on that phrase, please? 2 Q. Randomized controlled trial? 3 A. I understand what a randomized 4 controlled trial is to a certain level, but I 5 do not carry out analysis on clinical trials. 6 Q. In your research into this 7 matter, have you found any RCTs on humans to 8 determine whether NDMA is a human carcinogen? 9 A. I have not seen data to that 10 regard to show that humans have increased 11 levels of cancer following exposure to NDMA. 12 Q. The same question as it 13 pertains to NDEA. In your research into this 14 matter, have you found any randomized 15 controlled trials on humans to determine 16 whether NDEA is a human carcinogen? 17 A. I have not seen any clinical 18 trial, randomized controlled trial studies on 19 NDEA in humans to show that it's a human 20 carcinogen. I have not seen those data. 21 Q. Do you know whether it would be 22 ethical to conduct human trials using NDMA or 23 NDEA to determine if they're carcinogenic in 24 people?</p>
<p style="text-align: right;">Page 263</p> <p>1 the linear back-extrapolation approach, which 2 I have issues with. 3 Q. Do you agree that NDMA is a 4 genotoxic carcinogen? 5 A. I believe -- 6 MS. LOCKARD: Objection, form, 7 vague. 8 A. -- NDMA has been shown to be a 9 genotoxic carcinogen in animal studies, yes. 10 BY MS. BOGDAN: 11 Q. Do you agree that NDEA is a 12 genotoxic carcinogen? 13 MS. LOCKARD: Objection, form, 14 vague. 15 A. I believe that NDEA is a 16 genotoxic carcinogen in animals too. 17 BY MS. BOGDAN: 18 Q. Do you have an opinion whether 19 NDMA is a human carcinogen? 20 A. I believe that that has not 21 been shown to date through the data as I've 22 seen. 23 Q. Do you know what an RCT is? 24 A. Potentially. Could you expand</p>	<p style="text-align: right;">Page 265</p> <p>1 A. It's more that they would not 2 be practical. That's why we go with the 3 animal studies for such analyses for 4 genotoxic impurities. 5 Q. And why wouldn't they be 6 practical? 7 A. The rodent carcinogenicity 8 studies, these are lifetime studies. To do a 9 lifetime study in a human would take a lot 10 longer to generate the data, over, say, a 11 70-year period, then sacrifice the human at 12 the end of that and carry out pathology on 13 their organs, not practical. Two years, much 14 better than 70 years. 15 Q. Are you familiar with IARC? 16 A. I am. I have a familiarity 17 with IARC that carry out hazard assessments, 18 yes. 19 Q. And were you familiar with them 20 before your investigation into this case? 21 MS. LOCKARD: Objection, form, 22 the word "investigation." 23 A. I was aware of IARC before 24 this -- I've been aware of IARC for many</p>

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1 years.
2 BY MS. BOGDAN:
3 Q. In the field of toxicology, is
4 IARC looked to as a resource with regard to
5 evaluating the carcinogenic risk of chemicals
6 to humans?
7 A. No, it is not. It is to define
8 the hazard identified by these substances and
9 not the risk.
10 MS. BOGDAN: If we could please
11 pull up the exhibit IARC Monographs on
12 the Evaluation of the Carcinogenic
13 Risk of Chemicals to Humans.
14 (Whereupon, Deposition Exhibit
15 Johnson-22, 1978 IARC Monographs on
16 the Evaluation of the Carcinogenic
17 Risk of Chemicals to Humans, was
18 marked for identification.)
19 THE STENOGRAPHER: 22.
20 TRIAL TECHNICIAN: I don't see
21 this.
22 MS. BOGDAN: It's dated 1978,
23 the original one.
24 THE WITNESS: I have yet to

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1 receive it as an exhibit. Is it 22?
2 That may have just popped up. Is this
3 Exhibit 22?
4 MS. LOCKARD: Should be.
5 THE WITNESS: Right. It has
6 come up, very gray. I can see it,
7 yes.
8 BY MS. BOGDAN:
9 Q. What is the title of that
10 document?
11 A. IARC Monographs on the
12 Evaluation of the Carcinogenic Risk of
13 Chemicals to Humans.
14 Q. So does the title of that
15 document indicate to you that IARC monographs
16 are used to evaluate the carcinogenic risk of
17 chemicals to humans?
18 A. This title, presented in 1978,
19 was before the IARC announced that they were
20 actually a hazard-based organization more
21 recently. They do not talk about
22 concentrations and human exposure limits,
23 rather, yes/no, and categorizing them in
24 human carcinogen, probable carcinogen and so

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1 on, which is not risk. It's hazard.
2 Q. And evaluating whether or not a
3 chemical is a hazard to a human, would one of
4 those things or attributes that would make it
5 a hazard be that it's carcinogenic?
6 MS. LOCKARD: Objection, vague.
7 A. That would be one of the
8 aspects of hazards, as long as the data
9 abided to the OECD guideline on the cancer
10 bioassay for which these decisions could be
11 made. And this monograph predates the OECD
12 guideline for the cancer bioassay.
13 BY MS. BOGDAN:
14 Q. Now, when you're talking about
15 the OCD -- or OECD guideline for cancer
16 bioassay, you're talking about the guidelines
17 to run an animal test, correct?
18 A. A very specific animal test
19 where the species are defined, with rodent
20 being the preferred and very specific
21 criteria on study design.
22 Q. If we could go back to the
23 previous exhibit, which was the general
24 advice letter from the FDA, please. The next

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1 sentence that begins "In fact," do you see
2 that?
3 A. The one which you're
4 highlighting beginning "In fact," yes, I see
5 that.
6 Q. So that sentence reads: In
7 fact, N-nitroso compounds are identified as a
8 cohort of concern in internationally
9 harmonized guidance, ICH M7, Assessment and
10 Control of DNA Reactive (Mutagenic)
11 Impurities in Pharmaceuticals to Limit
12 Potential Carcinogenic Risk.
13 Do you see that sentence?
14 A. Yes, I see that sentence.
15 Q. Are you familiar with the
16 concept of "cohort of concern" that's
17 referred to in that sentence?
18 A. I'm very familiar with that
19 term.
20 Q. What does that term mean?
21 A. For genotoxic impurities,
22 they're of high importance, and that's why
23 the ICH M7 guideline really was prepared.
24 Within that, they came up with

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1 a concept, an applied concept called the
2 threshold for toxicological concern, where
3 they assessed all of the data from the cancer
4 potency database that used to reside in
5 Berkeley in the GOLD database that now
6 resides at Lhasa, took all of that
7 information, took the harmonic means from the
8 TD50s from the cancer bioassay dose-response
9 data, did a 1-in-100,000 level of risk
10 calculations or linear back-extrapolation,
11 one of the things that I push against with
12 the PDE based on threshold assumption.
13 And from the calculation for
14 the threshold of toxicological concern, a
15 proportion of the nitroso compounds were
16 shown to be more potent, the 1 in 100,000 at
17 the concentration of 1.5 micrograms per day
18 in humans. And that's all that means.
19 Q. And the ones that were shown to
20 be more potent, do those include NDMA and
21 NDEA?
22 A. That was not prescribed, but
23 the regulatory bodies have done the
24 acceptable intake space on those compounds.

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1 Q. And the regulatory bodies
2 followed the TD50 linear extrapolation
3 approach to come up with the acceptable
4 intakes; is that correct?
5 A. They did, yes.
6 Q. And when we're referring to
7 regulatory bodies, the TD50 linear
8 extrapolation approach is the one that's
9 followed by the FDA, correct, for NDMA and
10 NDEA?
11 A. It is the one that's followed
12 in order to generate the acceptable intakes
13 presented for NDMA and NDEA.
14 Q. And the EMA also followed the
15 TD50 linear extrapolation approach to come up
16 with the acceptable intakes for NDMA and
17 NDEA?
18 A. That is correct. On this
19 reactive response, they needed to carry out a
20 very quick and harmonized approach that
21 global regulatory bodies could do, where you
22 could get the harmonic means from the TD50,
23 CPDB database, and do a very simple linear
24 back-extrapolation, and come up with these

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1 acceptable intakes across the global platform
2 to generate these acceptable intakes.
3 Q. So the TD50 linear
4 back-extrapolation methodology for NDMA is
5 accepted by the FDA, correct?
6 A. It is accepted by the FDA, and
7 so is permitted daily exposure, as stated in
8 the ICH guidance.
9 Q. And the TD50 linear
10 back-extrapolation methodology for
11 determining acceptable intake of NDEA is
12 accepted by the FDA, correct?
13 A. That is correct. And they used
14 the linear back-extrapolation from the TD50
15 to generate the accepted intake, but within
16 the guidance, there's also an option for
17 other risk assessment approaches, including
18 the PDE.
19 Q. However, the FDA did not elect
20 to use any of those other approaches. They
21 used the linear back-extrapolation approach
22 using TD50 and the harmonic mean, correct?
23 A. Correct. To that time, in this
24 very reactive procedure, they -- they did

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1 make that decision, and then in the future
2 with further nitrosamines, when increased
3 information about mechanism of action,
4 dose response is included, then there will be
5 more options for the PDE as the science
6 catches up.
7 Q. The next sentence reads:
8 ICH M7 recommends that known mutagenic
9 carcinogens such as nitrosamines be
10 controlled at or below the acceptable cancer
11 risk level.
12 Is that what the ICH M7
13 recommends to your knowledge?
14 A. At the current time, to my
15 knowledge, that's the recommendation.
16 Q. Due to their known potent
17 carcinogenic effects, and because it is
18 feasible to limit these impurities by taking
19 reasonable steps to prevent or eliminate
20 their presence, the FDA has determined that
21 there is no acceptable specification for
22 nitrosamines in ARB, API and DP.
23 Is that your understanding of
24 the FDA's determination?

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1 MS. LOCKARD: Objection, form.
2 A. Yeah, from this statement I've
3 read and see that that's the statement from
4 the FDA, yes.
5 BY MS. BOGDAN:
6 Q. And in that sentence, if we
7 could highlight it, what does API stand for?
8 A. From my understanding, it means
9 active pharmaceutical ingredient.
10 Q. And what do the initials DP
11 stand for?
12 A. I'm unsure.
13 Q. Have you seen the initials DP
14 refer to drug product before?
15 A. I haven't seen it abbreviated
16 to DP. I see finished product, FP, more by
17 my colleagues in this area.
18 Q. And when someone takes a
19 medication, is the API the actual active
20 ingredient, the amount of the -- excuse me --
21 the amount of the active ingredient in the
22 tablet, meaning if you're taking valsartan
23 and it's 320 milligrams, it would be the
24 valsartan 320 milligrams that's contained in

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1 the tablet?
2 MS. LOCKARD: Objection, form.
3 A. Could you restate that question
4 again, please.
5 BY MS. BOGDAN:
6 Q. You said that API is the active
7 pharmaceutical ingredient, correct? Active
8 pharmaceutical ingredient. How does that
9 relate to a tablet that somebody takes?
10 A. This isn't my area of
11 expertise, but my understanding is the active
12 pharmaceutical ingredient is combined with
13 other substances for, say, different delivery
14 around the -- around the human in this
15 instance. So it's a part of the drug but not
16 the complete construction of the final drug,
17 or DP, in this instance.
18 Q. Are you an expert in
19 pharmaceutical manufacturing?
20 A. I'm not an expert in
21 pharmaceutical manufacturing.
22 MS. BOGDAN: We can take that
23 down.
24 ///

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1 BY MS. BOGDAN:
2 Q. What is a mutagen?
3 A. The definition in Europe is
4 that a mutagen is a substance that causes
5 gene mutations, and we assess for that with
6 mutagenicity tests in genetic toxicology.
7 There's some use in the U.S. by different
8 regulatory bodies that a mutagen covers all
9 types of genotoxicants.
10 Q. Do you differentiate between
11 the term "genotoxicants" and "mutagens"?
12 A. In -- I do, in this instance,
13 particularly when working with very important
14 substances where the mechanism of action is
15 mutation. We understand the mutation
16 mechanism. Definitely use the term
17 "mutagen."
18 Q. Does a mutagen change the DNA
19 sequence?
20 A. At the correct dose, the
21 mutagen can cause adducts, those DNA adducts
22 at certain places within the DNA, such as the
23 O6 position of guanine, which these compounds
24 can target, can leave an alkyl group on those

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1 specific positions in the DNA.
2 If those are left unrepaired by
3 the high levels of enzymes such as MGMT, and
4 if they're in a region where upon replication
5 they can be miscoded to another base, so upon
6 replication with the O6-alkylguanine lesion,
7 it would go from GC to AT.
8 And then that would go from
9 being an adduct to that specific area having
10 a mutation, and that mutation would have been
11 caused by that adduct.
12 Q. So in order to have a mutation,
13 the change in the DNA has to replicate,
14 correct?
15 A. In order for the adduct to go
16 into a mutation, it has to be misrecognized
17 as something else, and when it's
18 misrecognized as something else, another base
19 gets put opposite it, and that happens at the
20 DNA replication part of the cell cycle.
21 Q. How do mutations lead to
22 cancer?
23 A. Mutations can lead to cancer if
24 those mutations are in the coding region of

<p>Page 278</p> <p>1 DNA. Say 95% of our DNA is junk DNA that 2 wouldn't have a coding gene. Then also to 3 say the 25,000 other genes that we have, 4 there's some that are associated with cancer. 5 The broad term for those types 6 of genes are "oncogenes." If an oncogene is 7 upregulated through mutation, that leads to 8 increased proliferation, the hallmark of 9 cancer. 10 If a tumor suppressor gene -- 11 if there's a mutation which causes a tumor 12 suppressor gene to be silenced, then things 13 like DNA repair are not triggered. So if 14 there's mutations in this very specific 15 region of DNA and they're not picked up from 16 the DNA repair machinery, then they can lead 17 to cancer. 18 And a few of those genes -- say 19 most cancers would need, say, three to six 20 genes to be mutated before the cancer would 21 ensue, then at those concentrations of -- 22 those levels of mutation, those levels of 23 mutation could lead to cancer. That's my 24 explanation of it.</p> <p>Page 279</p> <p>1 Q. And is NDMA a mutagen? 2 A. NDMA is an alkylating agent and 3 it acts at those positions -- at that 4 position of guanine, which I mentioned. And 5 when we carried out mutation testing on NDMA, 6 we saw that it was a mutagen in the genetic 7 toxicology test system for mutation. 8 Q. Is NDEA a mutagen? 9 A. NDEA is a mutagen through a 10 very similar mechanism acting at the same 11 sort of adduct spectrum, mutation spectrum as 12 NDMA as well. 13 Q. Are they both alkylating agents? 14 A. The term is "alkylating agent." 15 Q. Oh, I'm sorry. Yeah. 16 A. Alkylating. 17 Q. Okay. 18 A. So NDMA and the metabolite of 19 NDMA can cause a CH₃ group, which is a methyl 20 group, and the broader term of a methyl group 21 would be under an alkyl group. So that's the 22 methylating part of that term. 23 And then NDEA could cause C₂H₅, 24 which would be an ethyl group, and that's</p>	<p>Page 280</p> <p>1 also under the blanket term of "alkyl." 2 So because of those substances 3 acting via that mechanism for causing DNA 4 adducts and then mutation, they can be termed 5 "alkylating agents" because they provide an 6 alkyl group to the DNA at certain 7 concentrations. 8 Q. Now, I've heard that they can 9 also, when they are metabolized into their 10 reactive form, form an ion. Is that true? 11 A. The ion, from my understanding, 12 the ion is the part with the methyl or ethyl 13 group, depending whether it's NDMA or NDEA 14 respectively. And that metabolite, that ion, 15 is the active group of that. 16 And because that requires -- to 17 get to that stage, requires metabolism 18 specifically from cytochrome P450 enzymes, 19 which are mostly found particularly at high 20 levels in the liver, that activity of that 21 ion causing those adduct mutations for these 22 substances is clearly identified in the 23 liver. 24 Q. Now, you mentioned the P450</p> <p>Page 281</p> <p>1 enzymes. Are they found elsewhere in the 2 human body other than the liver? 3 A. They are found at much lower 4 levels other than the liver. The liver's job 5 is really to be a metabolic powerhouse, and 6 because of that, the liver contains huge 7 amounts, high levels of these cytochrome 8 P450s than other organs, but as a residual, 9 at very low levels, they can be found 10 potentially in some other organs. But I'm 11 not an expert on those levels in other 12 organs. 13 Q. I was going to ask: Did you do 14 research into where the cytochrome P450s 15 exist in the human body other than the liver? 16 A. That was not part of my remit 17 and part of my report. I was looking at the 18 endpoints rather than the cytochrome P450 19 levels. Okay. 20 Q. What exactly were you asked to 21 do when you were hired as a consultant by 22 Teva in this litigation? 23 MS. LOCKARD: Objection, form, 24 vague.</p>
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<p>Page 282</p> <p>1 A. The exact remit of what I</p> <p>2 was -- what we discussed and what my report</p> <p>3 and risk assessment would include as</p> <p>4 supported by Teva and GT and later with the</p> <p>5 other defendants, at the time of initiation,</p> <p>6 because they had seen my presentation on the</p> <p>7 PDE in these different ways, it was very</p> <p>8 much: Can you expand on this report around</p> <p>9 PDEs and see how it applies to our situation.</p> <p>10 Beyond that, it was built on</p> <p>11 what I've already done, what I already know,</p> <p>12 and see how it applies to this situation.</p> <p>13 BY MS. BOGDAN:</p> <p>14 Q. And when you say they had seen</p> <p>15 my presentation on the PDE, what presentation</p> <p>16 are you referring to?</p> <p>17 A. This initiates from that</p> <p>18 Informa Impurities conference where I</p> <p>19 presented that work that we've discussed</p> <p>20 quite extensively already in Berlin where I</p> <p>21 had done the work with my regulatory</p> <p>22 colleagues, come up with some interesting</p> <p>23 findings, and presented them at that meeting.</p> <p>24 And really, it was just an</p>	<p>Page 284</p> <p>1 mutagens, for clastogens, for antigens.</p> <p>2 So under the blanket term of</p> <p>3 "genotoxic," mutagen becomes under that. And</p> <p>4 as I've already described, NDMA has been</p> <p>5 shown to be a mutagen in these in vitro and</p> <p>6 in vivo tests.</p> <p>7 Q. And then the same question with</p> <p>8 regard to NDEA because we're dealing with</p> <p>9 both compounds here, Doctor.</p> <p>10 Is NDEA genotoxic?</p> <p>11 A. Within the same definition,</p> <p>12 within -- under the term, blanket term</p> <p>13 "genotoxic" is the term "mutagen," so because</p> <p>14 I've already discussed around NDEA being</p> <p>15 assessed and shown to be a mutagen in vitro</p> <p>16 and in vivo with the standard tests, then we</p> <p>17 can say it's a mutagen, and we can say it's</p> <p>18 a -- and it's genotoxic.</p> <p>19 Q. And why are mutagens and</p> <p>20 genotoxins as far as chemicals a concern, if</p> <p>21 at all?</p> <p>22 A. At the right concentration, at</p> <p>23 a high concentration, the genotoxicant or --</p> <p>24 that would probably be something I'd talk</p>
<p>Page 283</p> <p>1 extension of what do these PDEs look like</p> <p>2 when you apply your numbers to the situation.</p> <p>3 Yes.</p> <p>4 Q. Who funded that original work</p> <p>5 you did that led to the presentation in</p> <p>6 Berlin, I believe you testified in 2018?</p> <p>7 MS. LOCKARD: Objection, asked</p> <p>8 and answered and vague.</p> <p>9 A. We discussed this extensively</p> <p>10 earlier to my recollection, and again, it was</p> <p>11 not funded. It was really research exercise</p> <p>12 triggered from my work with my regulatory</p> <p>13 experts and then expanded upon to the HESI</p> <p>14 GTTC.</p> <p>15 So I was not funded to carry</p> <p>16 out that initial work that was presented at</p> <p>17 that conference.</p> <p>18 Q. Is NDMA genotoxic?</p> <p>19 A. NDMA, in line with my</p> <p>20 description of the term "genotoxic," my</p> <p>21 description of the term "genotoxic" is in</p> <p>22 line with many of those experts in Europe</p> <p>23 where genotoxic is the all-encompassing</p> <p>24 power, the all-encompassing term for</p>	<p>Page 285</p> <p>1 about chromosomal, structural damage or</p> <p>2 chromosome loss, but I want to talk about</p> <p>3 mutation because that's relevant here.</p> <p>4 So we're trying to protect</p> <p>5 against increased levels of mutation by</p> <p>6 ensuring that high levels of mutagens and</p> <p>7 that people aren't exposed to them, because</p> <p>8 at high levels of mutagens, they cause</p> <p>9 mutation. High levels of mutation can lead</p> <p>10 to cancer at certain doses of a substance</p> <p>11 that is a mutagen.</p> <p>12 MS. BOGDAN: Okay. Can we pull</p> <p>13 back up the next exhibit that was</p> <p>14 already marked, which was that IARC</p> <p>15 monograph.</p> <p>16 TRIAL TECHNICIAN: Was that</p> <p>17 Exhibit 22?</p> <p>18 MS. BOGDAN: I believe so.</p> <p>19 It's the one right after the FDA</p> <p>20 letter. It was the last exhibit we</p> <p>21 marked.</p> <p>22 TRIAL TECHNICIAN: Okay.</p> <p>23 MS. BOGDAN: No, that's not it.</p> <p>24 It's the one that had the gray cover,</p>

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1 the IARC monograph dated 1978.
2 (Technical comments off the
3 stenographic record.)
4 BY MS. BOGDAN:
5 Q. Have you reviewed this document
6 as part of your investigation into this case?
7 A. I've considered this document,
8 but it didn't contribute to my decision
9 because the data within this predate the
10 guidance on how to carry out cancer
11 dose-response analysis in animals and also
12 predates the best cancer data in animals,
13 which would be the Peto data.
14 So because of that and this
15 being a hazard-based assessment on yes/no
16 rather than concentrations, I deemed this to
17 be obsolete and did not contribute to my
18 decisions and my risk assessment.
19 Q. Did you read through it?
20 A. I've read through parts of it
21 as a critique to my understanding that this
22 was used in another deposition, so I read
23 through it to look into it for that reason.
24 Q. If you could please turn to --

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1 it will not be page 88 in the PDF, but
2 page 88 marked as such in the bottom
3 left-hand corner.
4 A. All right. Okay. Mine starts
5 at 124.
6 TRIAL TECHNICIAN: Yeah, same,
7 125.
8 MS. BOGDAN: Can you go to
9 page 88?
10 TRIAL TECHNICIAN: No, it
11 starts at 125.
12 MS. BOGDAN: Okay. Well, then,
13 we'll go to page 125, which is the
14 Nitrosodimethylamine section, and then
15 from there, if we could go to page --
16 you just have a different version of
17 this than I have in front of me here,
18 so if we could go to page -- to
19 page 151.
20 THE WITNESS: I'm on page 151.
21 BY MS. BOGDAN:
22 Q. Okay. Do you see the section
23 that starts "Humans"?
24 A. Yes.

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1 Q. Okay. And the second
2 paragraph, it says: Studies in vitro suggest
3 that NDMA is metabolized by human liver and
4 lung via the same metabolic pathway as in
5 other mammalian species.
6 Do you see that?
7 A. I do see that.
8 Q. It's fuzzy. Okay.
9 Do you agree that the studies
10 that are available suggest that NDMA is
11 metabolized by humans via the same metabolic
12 pathway as in other mammals?
13 MS. LOCKARD: Objection to
14 form, vague.
15 A. As with a lot of information in
16 the IARC monographs, they don't talk about
17 levels at all. Studies in vitro suggest that
18 NDMA's metabolize by human liver and lung by
19 the same metabolic pathway.
20 That does not mean that there's
21 the same amount of -- same level of
22 metabolism in the lung as there is in the
23 liver. That's not stated here.
24 ///

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1 BY MS. BOGDAN:
2 Q. I was more interested in asking
3 your opinion -- I'm sorry. I -- I didn't
4 realize you weren't finished.
5 MS. LOCKARD: Go ahead,
6 Dr. Johnson.
7 A. Apologies. This is a very
8 vague statement from my perspective.
9 BY MS. BOGDAN:
10 Q. I was more interested in your
11 opinion regarding whether in your
12 investigation into this matter you formed any
13 opinion with regard to whether NDMA is
14 metabolized in humans in a similar way as in
15 other mammals.
16 MS. LOCKARD: Objection, form.
17 There's -- there's no question
18 pending.
19 A. Can you --
20 BY MS. BOGDAN:
21 Q. Do you have an opinion -- do
22 you have an opinion whether NDMA is
23 metabolized in humans in a similar way as
24 other mammals?

<p>Page 290</p> <p>1 A. I have an opinion that</p> <p>2 cytochrome P450 2E1 is able to metabolize</p> <p>3 NDMA in humans and in other organisms.</p> <p>4 Q. And when you say other</p> <p>5 organisms, is that mammals or some other type</p> <p>6 of organism?</p> <p>7 A. Specific to my report, where I</p> <p>8 focused on the rodents and the rodent cancer</p> <p>9 bioassay, then the presence and ability to</p> <p>10 metabolize NDMA by cytochrome P450 2E1, there</p> <p>11 is capacity for that in the rodent systems</p> <p>12 that we used. So in that regard, that's my</p> <p>13 answer.</p> <p>14 Q. So your answer is that in the</p> <p>15 rodent cancer bioassay testing, that it</p> <p>16 indicated that the rodents had the ability to</p> <p>17 metabolize NDMA by the cytokine P450s as NDMA</p> <p>18 is metabolized by humans?</p> <p>19 A. Yes, that was my understanding.</p> <p>20 And from my analysis and reading around that</p> <p>21 statement being correct, I'm comfortable with</p> <p>22 that statement.</p> <p>23 And also from my understanding</p> <p>24 of how these substances -- how NDMA causes</p>	<p>Page 292</p> <p>1 That's my understanding from</p> <p>2 the literature and from reading many</p> <p>3 different reports from different experts.</p> <p>4 Q. Do you have a particular study</p> <p>5 that you reviewed that you would cite to for</p> <p>6 the proposition that you just testified to?</p> <p>7 A. I'm aware that there's</p> <p>8 metabolism experts as another -- I was</p> <p>9 getting feedback. Has something changed?</p> <p>10 I'm getting feedback.</p> <p>11 Q. I heard a little feedback as</p> <p>12 well. It seems like it's cleared now.</p> <p>13 A. Okay. So I'm aware that</p> <p>14 there's a metabolism expert -- I potentially</p> <p>15 forgot the name -- but from the GT side that</p> <p>16 has been in line with this concept that the</p> <p>17 liver has the highest level of metabolism. I</p> <p>18 think it's Bottorff, but I may be corrected.</p> <p>19 And that's in line with my discussions.</p> <p>20 Also, because I work very</p> <p>21 closely with EMA and so forth, I realize all</p> <p>22 the risk assessments to date have also been</p> <p>23 on the liver, exactly down to this same</p> <p>24 issue, this same discussion point that the</p>
<p>Page 291</p> <p>1 mutation and then cancer at certain</p> <p>2 concentrations is why we can focus on the</p> <p>3 liver as being the target organ for the</p> <p>4 highest level of mutation and cancer as seen</p> <p>5 through the robust cancer bioassay and</p> <p>6 mutation test systems that I've included in</p> <p>7 my report. The downstream organs are lesser</p> <p>8 affected or not affected.</p> <p>9 So in that regards, that's my</p> <p>10 answer.</p> <p>11 Q. And that's based upon the</p> <p>12 information you derived from the rodent</p> <p>13 bioassays?</p> <p>14 A. And also an understanding of</p> <p>15 the metabolism of the substance. And I'm</p> <p>16 aware of experts in PK modeling and --</p> <p>17 pharmacokinetic modeling and distribution</p> <p>18 modeling that the analysis presented by such</p> <p>19 experts are that the substance, including</p> <p>20 NDMA, would reach the liver and be</p> <p>21 metabolized by those enzymes in the liver to</p> <p>22 the highest extent, potentially leaving not</p> <p>23 very much of that substance to go to</p> <p>24 downstream organs.</p>	<p>Page 293</p> <p>1 liver is the most metabolically competent</p> <p>2 organ for metabolizing this substance.</p> <p>3 And with all of that</p> <p>4 information together, that's where I come to</p> <p>5 my conclusion.</p> <p>6 Q. You testified earlier, I</p> <p>7 believe, that you had reviewed the other</p> <p>8 defendants' expert reports; is that correct?</p> <p>9 A. Some of them. And I considered</p> <p>10 them all.</p> <p>11 (Clarification requested by the</p> <p>12 stenographer.)</p> <p>13 BY MS. BOGDAN:</p> <p>14 Q. Did you consider some of them</p> <p>15 or consider them all? It was difficult to</p> <p>16 hear your response, Doctor.</p> <p>17 A. Oh, apologies. I've considered</p> <p>18 them all and assessed some of them.</p> <p>19 Q. And what's the difference</p> <p>20 between considering them and assessing them?</p> <p>21 A. My definition as I've just</p> <p>22 stated, considered would be is the report</p> <p>23 relevant to my report or to my understanding.</p> <p>24 If it's something like the epi experts, then</p>

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1 that would just be considered and not read in
2 detail.

3 If it was something more
4 relevant, something like the Hecht report, I
5 would read that in a fine level of detail, or
6 the Panigrahy one, for example, and then that
7 would -- I would carry it out in that way.

8 Q. Did you rely on, for example --
9 I think you mentioned Dr. Bottorff's report
10 with regard to the determination that the
11 liver was the target organ?

12 A. I did not. I made that
13 decision based on the risk assessments to
14 date that were all on the liver, as with all
15 the experts, understand that this is the case
16 for these substances, and from my reanalysis
17 of the in vivo cancer bioassay data as well,
18 for which the liver was always the most
19 sensitive and most important test tissue.

20 Q. When you reviewed the
21 defendants' expert reports, did you find
22 anything you disagreed with?

23 MS. LOCKARD: Objection, vague,
24 overbroad.

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1 Do you want him to reread them
2 and tell you what he disagrees with or
3 if he agrees with every statement?

4 MS. BOGDAN: Well, let me ask
5 the question a different way.

6 BY MS. BOGDAN:

7 Q. When you reviewed the
8 defendants' expert reports, was there
9 anything you took note of in their report
10 that you disagreed with?

11 A. I cannot recall.

12 Q. If we reviewed your list of
13 materials considered, would you be able to
14 tell me which expert reports you assessed?

15 A. I would not be beyond the
16 previous answer that I gave to this question.

17 Q. Would you be able to tell me
18 any of the experts by name that you read and
19 assessed their full report?

20 A. Can you repeat the last half
21 of -- the final sentence, please?

22 Q. Sure.

23 I said would you be able to
24 tell me any of the experts by name that you

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1 read and assessed their full report?

2 A. Dr. Hecht, Lagana, Panigrahy.
3 Potentially Etminan, but maybe I'm not so
4 confident. Let me get through.

5 I've read, I would say Chodosh.
6 And there's been other ones in there, say,
7 aspects of Bottorff, Raphael Nudelman, and
8 I've seen many of the others as well.

9 But off the top of my head,
10 maybe their names are more memorable. I can
11 agree to those ones.

12 Q. When -- if we could go back to
13 the exhibit, page 151, that's up on the
14 screen, when you reviewed the older studies,
15 did you find studies in different animal
16 species where NDMA was found to cause cancer?

17 MS. LOCKARD: Objection, form,
18 vague.

19 A. I looked at some of these -- I
20 think some of these are listed here -- and
21 the studies contributing to those decisions.
22 I think one of the experts expanded on many
23 of these studies in their report.

24 So due to that, I looked at

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1 those reports to see if the cancer studies
2 within these test systems looked to be of
3 suitable study design, say, were they the
4 right route of exposure, or were they
5 intraperitoneal injections? Were they
6 swimming in crazy -- like very high
7 concentrations of the substance?

8 Really to see if the test -- if
9 the study design was anything close to the
10 OECD guidelines, which this document, again,
11 predates, to make it so any of these findings
12 were able to contribute to my decision.

13 And I found issues with all of
14 the study designs that I looked at, mostly
15 based on route of administration, very high
16 concentrations, no dose response. It's also
17 precancer bioassay OECD guideline, which
18 means that not even the animal husbandry,
19 things like that were consistent, preparation
20 of dosing. Basically, nothing can be
21 reliable from such a test.

22 And that's the kind of
23 considerations that I went through. In
24 considering how incredible datasets such as

<p>Page 298</p> <p>1 the Peto dose-response data and those that</p> <p>2 reside in the cancer potency database for</p> <p>3 this actual risk assessment are not this</p> <p>4 preliminary, really issue-based hazard</p> <p>5 assessment from IARC, then I found many</p> <p>6 issues in these studies.</p> <p>7 BY MS. BOGDAN:</p> <p>8 Q. If we could please go to</p> <p>9 page 152. You see the section that's</p> <p>10 entitled Evaluation?</p> <p>11 A. I can see the section.</p> <p>12 Q. Okay. And in that evaluation,</p> <p>13 which again, was done in 1978 --</p> <p>14 A. Yeah.</p> <p>15 Q. -- it reads: There is</p> <p>16 sufficient evidence of carcinogenic effect of</p> <p>17 N-nitrosodimethylamine in many experimental</p> <p>18 animals.</p> <p>19 A. Based on --</p> <p>20 Q. Do you --</p> <p>21 MS. LOCKARD: Hold on.</p> <p>22 (Simultaneous discussion</p> <p>23 interrupted by the stenographer.)</p> <p>24 ///</p>	<p>Page 300</p> <p>1 Similarities in its metabolism by human and</p> <p>2 rodent tissues have been demonstrated.</p> <p>3 And then it reads on: Although</p> <p>4 no epidemiological data were available -- and</p> <p>5 then it says -- and efforts should be</p> <p>6 directed toward this end,</p> <p>7 N-nitrosodimethylamine should be regarded for</p> <p>8 practical purposes as if it were carcinogenic</p> <p>9 to humans.</p> <p>10 Was that the guidance that was</p> <p>11 given by IARC back in 1978?</p> <p>12 A. That looks to be the guidance</p> <p>13 provided by IARC in 1978, but it looks like</p> <p>14 with their updated definition, that it will</p> <p>15 be probable human carcinogen.</p> <p>16 MS. BOGDAN: Can we please mark</p> <p>17 the IARC monograph dated 1987.</p> <p>18 (Whereupon, Deposition Exhibit</p> <p>19 Johnson-23, 1987 IARC Monographs on</p> <p>20 the Evaluation of the Carcinogenic</p> <p>21 Risk of Chemicals to Humans, was</p> <p>22 marked for identification.)</p> <p>23 MS. BOGDAN: Can I have a check</p> <p>24 on the time?</p>
<p>Page 299</p> <p>1 BY MS. BOGDAN:</p> <p>2 Q. There's a little bit of a</p> <p>3 delay. Do you agree with that statement?</p> <p>4 A. I believe that that's their</p> <p>5 statement, but it's based on very flawed</p> <p>6 experimental designs, predating the cancer</p> <p>7 bioassay guideline and obsolete to my report,</p> <p>8 and this is hazard-based too.</p> <p>9 Q. Well, the Peto study that</p> <p>10 you're referencing, which came along later,</p> <p>11 if I'm remembering, maybe 1991, correct,</p> <p>12 thereabouts?</p> <p>13 A. Yes, correct, thereabouts.</p> <p>14 Q. That -- that study provided</p> <p>15 evidence of a carcinogenic effect of</p> <p>16 N-nitrosodimethylamine, didn't it?</p> <p>17 MS. LOCKARD: Objection, form,</p> <p>18 vague.</p> <p>19 A. It provided carcinogenicity at</p> <p>20 certain doses in that study in those -- in</p> <p>21 that test system.</p> <p>22 BY MS. BOGDAN:</p> <p>23 Q. And then reading on, the</p> <p>24 statement by IARC back in 1978 was:</p>	<p>Page 301</p> <p>1 THE STENOGRAPHER: You are at</p> <p>2 6 hours, 52.</p> <p>3 And this is Exhibit 23.</p> <p>4 BY MS. BOGDAN:</p> <p>5 Q. Have you reviewed this document</p> <p>6 or are you familiar with it?</p> <p>7 A. Apologies. It's not up yet.</p> <p>8 Which exhibit again, please?</p> <p>9 THE STENOGRAPHER: 23.</p> <p>10 THE WITNESS: Yeah, it's still</p> <p>11 not up for me, apologies. It's</p> <p>12 appeared now. I'm just loading it.</p> <p>13 MS. BOGDAN: Okay.</p> <p>14 THE WITNESS: Okay. Here we</p> <p>15 go. I've got it.</p> <p>16 BY MS. BOGDAN:</p> <p>17 Q. All right. And, this document,</p> <p>18 if you can see it, is an IARC monograph as</p> <p>19 well, and it's an update to the IARC</p> <p>20 monographs. And this document was produced</p> <p>21 in 1987.</p> <p>22 Can you see that?</p> <p>23 A. I can see that, again,</p> <p>24 predating the Peto study, which is</p>

<p>Page 302</p> <p>1 interesting.</p> <p>2 Q. Okay. And then are you</p> <p>3 familiar with the different classifications</p> <p>4 that IARC has developed for the different</p> <p>5 chemicals?</p> <p>6 A. I am. I'm aware of their</p> <p>7 hazard-based classifications of these</p> <p>8 chemicals.</p> <p>9 Q. Do you know what IARC has</p> <p>10 graded NDMA?</p> <p>11 MS. LOCKARD: Object to form,</p> <p>12 vague, misstates the document.</p> <p>13 A. My understanding is a probable</p> <p>14 human carcinogen.</p> <p>15 BY MS. BOGDAN:</p> <p>16 Q. If we could go to page 31 of</p> <p>17 this document. And the page numbers are on</p> <p>18 the upper inside corner.</p> <p>19 A. Almost there.</p> <p>20 Q. If I could direct your</p> <p>21 attention to the very last paragraph, which</p> <p>22 starts with "Group 2A."</p> <p>23 A. I'm still finding it. My PDF</p> <p>24 reader is saying the pages are different.</p>	<p>Page 304</p> <p>1 classified into this category solely on the</p> <p>2 basis of limited evidence of carcinogenicity</p> <p>3 in humans or of sufficient evidence of</p> <p>4 carcinogenicity in experimental animals</p> <p>5 strengthened by supporting evidence from</p> <p>6 other relevant data.</p> <p>7 Q. And is that your understanding</p> <p>8 of the 2A classification by IARC for a</p> <p>9 probable human carcinogen?</p> <p>10 A. That is my interpretation of</p> <p>11 their classification of 2A, a probable human</p> <p>12 carcinogen, yeah.</p> <p>13 Q. If we can go to page 42 of the</p> <p>14 document, and where it says: Group 2A. The</p> <p>15 working group concluded that the following</p> <p>16 agents are probably carcinogenic to humans.</p> <p>17 Do you see that?</p> <p>18 A. Yes, I see that.</p> <p>19 Q. And directing your attention</p> <p>20 down the list, about seven from the bottom,</p> <p>21 do you see N-nitrosodiethylamine?</p> <p>22 A. Yes, I do.</p> <p>23 Q. And N-nitrosodimethylamine?</p> <p>24 A. Yes, I do.</p>
<p>Page 303</p> <p>1 Group 2A, I think I found it.</p> <p>2 Q. Okay. I think it's also been</p> <p>3 put up maybe a little larger on the screen so</p> <p>4 you can see it.</p> <p>5 A. Oh. I'll go with the Zoom</p> <p>6 screen for this. Thank you.</p> <p>7 Q. Is it your understanding that</p> <p>8 IARC has classified NDMA and NDEA as a</p> <p>9 Group 2A chemical?</p> <p>10 A. It is my understanding that</p> <p>11 they've classified NDMA and NDEA as probably</p> <p>12 carcinogenic to humans based on this</p> <p>13 hazard-based assessment, yes.</p> <p>14 Q. Can you read the description</p> <p>15 that IARC has for the agent is probably</p> <p>16 carcinogenic to humans?</p> <p>17 A. Which sentence --</p> <p>18 Q. You can read them all in its</p> <p>19 entirety.</p> <p>20 A. Okay. This category is used</p> <p>21 when there is limited evidence of</p> <p>22 carcinogenicity in humans and sufficient</p> <p>23 evidence of carcinogenicity in experimental</p> <p>24 animals. Exceptionally, an agent may be</p>	<p>Page 305</p> <p>1 Q. And this document is</p> <p>2 classifying them as, if we look at the top,</p> <p>3 probably carcinogenic to humans, correct?</p> <p>4 A. According to their definition</p> <p>5 of that with no consideration of dose, just</p> <p>6 in a hazard-based assignment, they're</p> <p>7 probably carcinogenic to humans, correct,</p> <p>8 according to their classification.</p> <p>9 Q. Okay. Thank you.</p> <p>10 MS. BOGDAN: Can we go off the</p> <p>11 record, please.</p> <p>12 THE VIDEOGRAPHER: Going off</p> <p>13 the record. The time is 5:38 p.m.</p> <p>14 (Discussion off the record.)</p> <p>15 (Whereupon, the following</p> <p>16 proceedings were conducted off the</p> <p>17 videotaped record.)</p> <p>18 MS. LOCKARD: So we're back on</p> <p>19 the record after having taken a break.</p> <p>20 I just want to make the record</p> <p>21 clear that plaintiffs' counsel is</p> <p>22 stopping the deposition after we've</p> <p>23 been on the record now for less than</p> <p>24 7 hours.</p>

<p style="text-align: right;">Page 306</p> <p>1 It's our expectation that, you</p> <p>2 know, the option for going into a</p> <p>3 second day is when it cannot be</p> <p>4 finished in the first day.</p> <p>5 It's only 12:39 p.m. on</p> <p>6 East Coast time currently, so for the</p> <p>7 record, we are ready and willing to</p> <p>8 continue moving forward with the</p> <p>9 deposition.</p> <p>10 We have international flights</p> <p>11 tomorrow night that we have to make,</p> <p>12 so if -- you know, if we're going to</p> <p>13 stop now, I just want to make sure the</p> <p>14 record is clear we're going to have to</p> <p>15 plow through tomorrow because we're</p> <p>16 not changing our flights because we</p> <p>17 stopped at, you know, 12:30 on Eastern</p> <p>18 Time.</p> <p>19 MS. BOGDAN: And just so the</p> <p>20 record is clear, we began this</p> <p>21 deposition at 4:00 a.m. Eastern Time,</p> <p>22 so we have been at this over 8, almost</p> <p>23 9 hours, and had to, obviously, get up</p> <p>24 and be here.</p>	<p style="text-align: right;">Page 308</p> <p>1 we're not going to have time for</p> <p>2 breaks. We're going to have to go --</p> <p>3 I mean, very short breaks, but we're</p> <p>4 going to have to go through.</p> <p>5 MS. BOGDAN: What time is your</p> <p>6 flight tomorrow?</p> <p>7 MS. LOCKARD: He's got to leave</p> <p>8 for the airport, my colleague, at 2:00</p> <p>9 to make the flight.</p> <p>10 So, I mean, we assumed that we</p> <p>11 would push through today and get</p> <p>12 there, you know, do the last bit</p> <p>13 tomorrow. But if we're -- if you're</p> <p>14 taking 10 hours on the record, I</p> <p>15 just want to be clear, we're not going</p> <p>16 to push late tomorrow, so...</p> <p>17 MS. GOLDENBERG: I mean, that's</p> <p>18 3 hours of testimony in 5 hours of</p> <p>19 time. I think we should be okay.</p> <p>20 MS. LOCKARD: Well, I'm just</p> <p>21 making our position known so there's</p> <p>22 no dispute about it tomorrow. And</p> <p>23 we'll start tomorrow at the same time.</p> <p>24 THE STENOGRAPHER: Anything</p>
<p style="text-align: right;">Page 307</p> <p>1 Victoria, I don't know what</p> <p>2 time your flights are tomorrow. We</p> <p>3 noticed the deposition for two days.</p> <p>4 And we have done -- when you</p> <p>5 say under 7 hours of record time,</p> <p>6 well, 6 hours and 58 minutes is, in my</p> <p>7 opinion, about 7 hours of record time.</p> <p>8 So I don't understand why there</p> <p>9 would be any reason that we could not</p> <p>10 start at, again, 4:00 a.m. Eastern</p> <p>11 Standard Time tomorrow and continue to</p> <p>12 take the deposition.</p> <p>13 I don't know what time your</p> <p>14 flights are, but, you know, given the</p> <p>15 fact that this is a two-day</p> <p>16 deposition, I just don't think that's</p> <p>17 a justification for not being able to</p> <p>18 conclude this.</p> <p>19 THE STENOGRAPHER: Anything</p> <p>20 else?</p> <p>21 MS. LOCKARD: Yeah.</p> <p>22 The only other thing I'm saying</p> <p>23 is if we're stopping now, tomorrow, if</p> <p>24 we're starting in the morning at 9:00,</p>	<p style="text-align: right;">Page 309</p> <p>1 else for the record?</p> <p>2 MS. BOGDAN: Did Marlene's</p> <p>3 statement get on the record? Because</p> <p>4 I was going to say the same thing.</p> <p>5 MS. LOCKARD: It did. It's on</p> <p>6 the record.</p> <p>7 I mean, obviously, I'm going to</p> <p>8 have questioning too, so -- but we can</p> <p>9 go off the record. We'll start at</p> <p>10 9:00 a.m. tomorrow.</p> <p>11 THE STENOGRAPHER: Off the</p> <p>12 record.</p> <p>13 (Time noted: 5:43 p.m. BST)</p> <p>14 --oOo--</p> <p>15</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p>

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1 CERTIFICATE
 2 I, MICHAEL E. MILLER, Fellow of
 3 the Academy of Professional Reporters,
 4 Registered Diplomate Reporter, Certified
 5 Realtime Reporter, Certified Court Reporter
 6 and Notary Public, do hereby certify that
 7 prior to the commencement of the examination,
 8 GEORGE JOHNSON, Ph.D. was duly sworn by me to
 9 testify to the truth, the whole truth and
 10 nothing but the truth.
 11 I DO FURTHER CERTIFY that the
 12 foregoing is a verbatim transcript of the
 13 testimony as taken stenographically by and
 14 before me at the time, place and on the date
 15 hereinbefore set forth, to the best of my
 16 ability.
 17 I DO FURTHER CERTIFY that pursuant
 18 to FRCP Rule 30, signature of the witness was
 19 not requested by the witness or other party
 20 before the conclusion of the deposition.
 21 I DO FURTHER CERTIFY that I am
 22 neither a relative nor employee nor attorney
 23 nor counsel of any of the parties to this
 24 action, and that I am neither a relative nor
 employee of such attorney or counsel, and
 that I am not financially interested in the
 action.
 MICHAEL E. MILLER, FAPR, RDR, CRR
 Fellow of the Academy of Professional Reporters
 NCRA Registered Diplomate Reporter
 NCRA Certified Realtime Reporter
 Certified Court Reporter
 New Jersey Certified Court Reporter
 No. 30X100242200
 Expires: 6/30/2022
 Dated: October 18, 2021

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1 INSTRUCTIONS TO WITNESS
 2
 3 Please read your deposition over
 4 carefully and make any necessary corrections.
 5 You should state the reason in the
 6 appropriate space on the errata sheet for any
 7 corrections that are made.
 8 After doing so, please sign the
 9 errata sheet and date it.
 10 You are signing same subject to
 11 the changes you have noted on the errata
 12 sheet, which will be attached to your
 13 deposition.
 14 It is imperative that you return
 15 the original errata sheet to the deposing
 16 attorney within thirty (30) days of receipt
 17 of the deposition transcript by you. If you
 18 fail to do so, the deposition transcript may
 19 be deemed to be accurate and may be used in
 20 court.
 21
 22
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 24

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1 ERRATA
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1 ACKNOWLEDGMENT OF DEPONENT
 2
 3
 4 I, GEORGE JOHNSON, Ph.D., do
 5 hereby certify that I have read the foregoing
 6 pages and that the same is a correct
 7 transcription of the answers given by me to
 8 the questions therein propounded, except for
 9 the corrections or changes in form or
 10 substance, if any, noted in the attached
 11 Errata Sheet.
 12
 13 _____
 14 GEORGE JOHNSON, Ph.D. DATE
 15
 16 Subscribed and sworn to before me this
 17 _____ day of _____, 20 _____.
 18 My commission expires: _____
 19 _____
 20 Notary Public
 21
 22
 23
 24

1	LAWYER'S NOTES		
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Errata Sheet

October 4-5, 2021 Deposition Transcript – George Johnson, Ph.D.
In re: Valsartan, Losartan, and Irbesartan Products Liability Litigation

MONDAY 10/4/21

Pages, Lines	Change:	Reason
64:24	Change “test” to “ testing ”	Clarification
83:23	Change “I’ve” to “ I ”	Clarification
94:10	Change “how it’s occurred” to “ how it occurs ”	Clarification
157:23	Change “slide date” to “slide deck ”	Clarification.
174:13	Change “replied” to “ replying ”	Clarification
192:6-7	“or if, as we predicted, the observed concentration would be below the PDE...”	Clarification
199:23	Change “contour” to “ quantal ”	Transcription error
205:12	Change “covariant” to “ covariate ”	Transcription error
219:17	Change “was” to “ were ”	Transcription error / Correction
258:20	“I did, (as in “what I did was”))” – should edit to say, “What I did was, I looked at	Transcription error / Correction

TUESDAY 10/5/21

Pages, Lines	Change:	Reason
328:2	Add: “and even then it will not be 100% pure.”	Completeness / clarification
340:22	Change “multiples suggested” to read “multiple <i>species</i> ” suggested by....	Transcription error / clarification.
351:11-13	Remove names; incorrect recollection, these persons not involved.	Correction
377:11-12	Change “lie to” and make it “ align with ”	Transcription error / correct testimony
379:3	Change “far” to “ for ”	Transcription error / correct testimony
381:6	Insert “ do not ” before have	Transcription error / correct testimony
384:5	Change 1-100 risk to 1-100,000	Transcription error / correct testimony
384:6	Change 1-100 risk to 1-100,000	Transcription error / correct testimony
387:1-2	Edit “That’s the background” to “ That’s the actual background rate of cancer. ”	Completeness and clarification
421:3	Delete “would be”	Correction / Clarification
445:20	Change “antigens” to “ aneugens ”	Transcription error / correct testimony

446:21	Change "vice president" to " past president "	Transcription error / correct testimony
460:1	Change "is it shows" to "is that it shows"	Clarification
463:12	Strike "I do"	Clarification
492:6	Change "talking" to " talk "	clarification
495:21	Change "To say" to " For example "	Clarification
507:13	Change "yeah" to " yes "	Proper English
518:24	Add comma after "would be,"	Clarification on sentence



George Johnson, Ph.D.

 _____, Notary Public.

This, the 17th day of November, 2021.

My Commission Expires:

